June 6, 2000

MEMORANDUM

SUBJECT: **Propargite**; Chemical No. 097601. HED's Revised Human Health Risk

Assessment for Propargite, Case # 0243. DP Barcode: D266000.

From: Thurston G. Morton, Risk Assessor

Reregistration Branch 4

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Attached is HED's revised human health risk assessment for the acaricide, propargite. The disciplinary science chapters and other supporting documents for Propargite are included as attachments as follows:

Propargite - Report of the Hazard Identification Assessment Review Committee. J.Rowland/P. Wagner (6/22/99)

Propargite - Report of the FQPA Safety Factor Committee. B. Tarplee/J. Rowland (8/12/99)

Revised Q1* Memorandum (L. Brunsman, 11/23/99)

Product & Residue Chemistry Chapter. J. Stokes (1/20/00, D250257)

Revised Toxicology Chapter. S. Shallal (5/24/00, D266213)

Revised Occupational and Residential Exposure Assessment. S. Tadayon (6/6/00, D266207)

Revised Anticipated Residues and Acute, Chronic, and Cancer Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment. T. Morton (5/24/00, D266001)

Review of Propargite Incident Reports. J. Blondell/M. Spann (12/8/99, D261208)

1.0 EXECUTIVE SUMMARY

Propargite [2-(p-tert-butylphenoxy)cyclohexyl-2-propynyl sulfite] is a non-systemic acaricide currently registered for food/feed uses on a variety of field, fruit, and vegetable crops. Tolerances for residues of propargite in/on food and feed commodities are currently established under 40 CFR §180.259(a) and (b), §185.5000, and §186.5000(a) and are expressed in terms of propargite *per se*.

Hazard Identification

Propargite is an organosulfite acaricide used for the control of agricultural pests. The toxicological database for propargite is complete (See Table 1) and will support reregistration eligibility. In general, based on animal studies, propargite has low acute toxicity via the oral, dermal, and inhalation routes of exposure (Category III), but causes severe eye and skin irritation (Category I).

Propargite is considered **corrosive** and has been placed in Category I **for both eye and dermal irritation** in rabbits. There have also been documented reports of dermal and eye irritation developing in workers exposed to propargite in the field. Evidence for its dermal sensitization potential have been noted; a study that provides conclusive results has not been possible due to the irritating properties of this chemical.

Toxicity Doses And Endpoints Selected For Risk Assessment

On June 3, 1999, the Health Effects Division (HED) Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology database of propargite, established Reference Doses (RfDs), and selected the toxicological endpoints and doses for occupational exposure risk assessments. All endpoints are based solely on animal toxicity studies.

For acute dietary risk assessment, the NOAEL of 8 mg/kg/day from a developmental toxicity study in rabbits was chosen based on increased incidence of fetuses with fused sternebrae at the LOAEL of 10 mg/kg/day. The acute RfD was calculated using a 10x interspecies and 10x intraspecies uncertainty factor. The acute Population Adjusted Dose (aPAD) was 0.08 mg/kg/day (acute RfD 0.08 mg/kg/day \div 1x FQPA safety factor) and is applicable to Females 13-50 years only.

The HIARC reaffirmed use of an RfD of 0.04 mg/kg/day for chronic dietary risk assessments based on the results of a chronic feeding and carcinogenicity study in rats in which the NOAEL was 4 mg/kg/day. The NOAEL of 4 mg/kg/day was based on decreased body weight / body weight gain and increased mortality at the LOAEL of 19 mg/kg/day. The chronic Population Adjusted Dose (cPAD) was 0.04 mg/kg/day (chronic RfD 0.04 mg/kg/day ÷ 1X FQPA safety factor).

For estimating dermal risk, short- and intermediate-term animal studies reflecting oral

administration of the pesticide were used, along with a dermal absorption factor of 14%. A 14% dermal absorption factor was selected based on the highest absorption/elimination noted in two submitted studies. This percentage is deemed valid since it corresponds to the amount of propargite which was actually detected in the excretions of animals. For short-term dermal risk assessments, a NOAEL of 6 mg/kg/day was selected based on decreased maternal body weight gain at the maternal systemic oral LOAEL of 8 mg/kg/day in a developmental toxicity study in rabbits. For intermediate-term dermal risk assessments, a NOAEL of 4 mg/kg/day was selected based on reduction in body weight at a parental oral LOAEL of 20 mg/kg/day in a reproductive toxicity study in rats. For long-term dermal risk assessments, a NOAEL of 4 mg/kg/day was selected based on decreased body weight/body weight gain and increased mortality in a chronic feeding and carcinogenicity study in rats at a LOAEL of 20 mg/kg/day. For inhalation exposure risk assessments at all durations, a LOAEL of 0.31 mg/L (50 mg/kg/day) was chosen based on increased mortality in males in an acute inhalation study in rats. The target MOE is 100 for dermal occupational risk assessments. The target MOE is 1000 for inhalation exposure risk assessments because of an additional 10x due to the lack of a NOAEL and the severity of effects at the lowest dose tested.

On January 23, 1992, the Cancer Peer Review Committee (CPRC) determined that based on the evidence presented, propargite was classified a Group B2, "likely" human carcinogen. It was concluded that administration of propargite was associated with the appearance of extremely rare jejunal tumors in male and female Sprague-Dawley rats. There was an increase in the incidence of undifferentiated sarcoma of the jejunum in males and females receiving 800 ppm propargite compared to concurrent and historical controls. A Q_1^* for propargite was calculated as 2.01 X 10^{-1} (mg/kg/day)⁻¹ using the 3/4 scaling factor as documented in a memo by Lori Brunsman dated November 23, 1999.

The FQPA Safety Factor Committee met on August 9,1999 to evaluate hazard and exposure data for propargite and recommend application of the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996), to ensure the protection of infants and children from exposure to propargite. Based on the following: 1) lack of increased susceptibility following *in utero* exposure to rats and rabbits and pre/post natal exposure to rats; 2) adequacy of the database; 3) no currently registered residential uses; and 4) the exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of propargite, the FQPA committee recommended reduction of the FQPA Safety Factor to 1X.

Dietary Exposure and Risk Assessment (General Population)

Registered propargite end-use products include emulsifiable concentrate (EC) and wettable powder (WP) formulations. Depending on the crops, these formulations may be applied as broadcast, banded or directed spray or chemigation foliar treatments pre- or postharvest using ground or aerial equipment. Single application rates range from 0.8 to 4.5 pounds per acre. Preharvest intervals range from 7 to 60 days. The nature of the residue in plants and animals is

adequately understood. The HED Metabolism Assessment Review Committee (MARC) concluded the residue of concern in plants and animals is propargite *per se*. Analytical methods are available for enforcing propargite tolerances in PAM II. For most commodities, adequate storage stability data are available. Additional storage stability data are required for an oily commodity to support residue studies on peanut and walnut, and storage stability data are required to support corn and peanut processing studies.

Adequate field trials are available pending submission of required storage stability data, sample storage information, or required label amendments. Adequate processing studies have been submitted for potatoes, citrus, field corn, grapes and peanuts. However, storage stability data are required to support the corn and peanut processing studies.

The reregistration requirements for animal feeding studies are fulfilled. Acceptable ruminant and poultry feeding studies have been submitted and evaluated.

The metabolism of propargite in rotated crops is similar to that in primary crops. Based on an adequate confined rotational crop study and limited field rotational crop studies, the Agency concluded that a six-month plantback interval (PBI) for root crops and a two-month PBI for all other crops are acceptable.

Estimated acute dietary exposure is below HED's level of concern for all female subpopulations at the 99.9th percentile. Use of USDA Pesticide Data Program (PDP) monitoring data, field trial data, and calculated livestock anticipated residues (ARs) results in a dietary risk estimate of 2 % of the aPAD for Females (13-50 years).

Estimated chronic dietary exposure is below HED's level of concern. Use of PDP monitoring data, field trial data, and calculated livestock ARs results in a maximum risk of <1 % of the chronic PAD (% cPAD) for the U.S. Population and all subpopulations.

The cancer dietary exposure and risk estimate for propargite is 1.2 X 10⁻⁶. Results of the analyses indicate potential residues in milk are one of the contributors to the estimated exposure and risk. There were no detections of propargite in PDP data for milk and the highest residue in the 2x feeding study was at the 0.011 ppm. A sensitivity analysis was performed by inserting zeroes for the milk commodities resulting in a cancer dietary exposure and risk estimate of 1.0 X 10⁻⁶.

Acute drinking water levels of concern (DWLOCs) were calculated based on the acute dietary (food) exposure and default body weights and water consumption figures. The acute DWLOC for Females 13-50 years is 2400 ppb. The EECs for surface water (GENEEC) and groundwater (SCI-GROW) were less than the acute DWLOC's, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The peak GENEEC EEC was 69 ppb, while the estimated groundwater EEC was 0.006 ppb.

The EECs for surface water (GENEEC) and groundwater (SCI-GROW) were less than the chronic DWLOCs, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The average GENEEC EEC was 7.6 ppb, while the estimated SCI-GROW EEC was 0.006 ppb.

Cancer DWLOCs were not calculated because cancer dietary (food) risk was at 1.0 X 10⁻⁶. Exposure to propargite from drinking water derived from groundwater sources is minimal and would not contribute significantly to the cancer risk. Surface water concentrations below 0.2 ppb would result in cancer risks below 1 X 10⁻⁶ for drinking water alone when back calculated. Time weighted average propargite concentration in surface water samples from the USGS NAWQA (Oristimba Creek Watershed) for the years 1992-1993 were 0.30 and 1.24 ppb, respectively. Therefore, even when monitoring data are used cancer exposure to propargite from surface water sources is greater than HED's level of concern.

Occupational Exposure and Risk Assessment

Registered propargite end-use products include emulsifiable concentrate (EC) and wettable powder (WP) formulations. Depending on the crops, these formulations may be applied as broadcast, banded or directed spray or chemigation foliar treatments pre- or postharvest using ground or aerial equipment. Single application rates range from 0.8 to 4.5 pounds per acre. Preharvest intervals range from 7 to 60 days. EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with propargite. Based on the use patterns and potential exposures described above, 14 major agricultural exposure scenarios are identified in this document to represent the extent of propargite uses.

Short-term handler exposure scenarios resulted in risk estimates expressed as MOEs, ranging from less than 1 to 2,570. A total of 71 exposure scenarios were evaluated for the various application rates assessed in each scenario. Based on the maximum level of protection (e.g., various levels of PPE or engineering controls) all scenarios had MOEs estimated to be greater than 100.

The results of the **intermediate-term handler** assessments indicate that all potential exposure scenarios provide at least one application rate with a total MOE(s) greater than or equal to 100 at either the **maximum PPE** (i.e., long pants, long sleeved shirts, and chemical resistant gloves while using open systems) or using **engineering controls** (i.e., closed systems). In the majority of

cases, it is dermal exposure rather than the inhalation exposure contributing most to the exposure estimate (dermal and inhalation exposures were not combined). More specifically, the MOEs for all the scenarios range from 1 to 2,000. In total, 70 MOEs were calculated for the various application rates. Based on the maximum level of protection (i.e., various levels of PPE or engineering controls) all MOEs are greater than 100.

The baseline cancer risk estimates for handlers ranged from 1.2E-2 to 8.2E-6. When engineering controls were added the cancer risk was mitigated to 1.1E-4 to 8.4E-7.

For occupational **postapplication** exposure, propargite exposure estimates have MOEs equal to or exceeding 100 for all scenarios. Current propargite labels allow reentry in 48 hours. Field worker experience and reported incident data suggest that the skin irritation of propargite can be severe for several days after treatment. Longer REIs established in this document would help reduce incidents. This has been demonstrated in California when they extended the REIs in 1991 for various agricultural crops.

Residential Exposure and Risk Assessment

There are no registered residential uses of propargite.

This assessment reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the *Draft: Series 875-Occupational and Residential Exposure Test Guidelines, Group B-Postapplication Exposure Monitoring Test Guidelines (7/24/97 Version)*, the *Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment (12/11/97 Version)*, and the *Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment* presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments. Modifications to this assessment shall be incorporated as updated guidance becomes available and it is feasible from a regulatory perspective. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources already not addressed such as from spray drift; residential residue track-in; exposures to farmworker children; and exposures to children in schools.

Aggregate Risk Assessment

There are no registered residential uses of propargite, so aggregation would contain only food and water risk estimates.

Acute aggregate risk estimates do not exceed HED's level of concern. The estimated environmental concentrations (EECs) for surface water (GENEEC) were less than the acute DWLOCs, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The acute DWLOC for Females 13-50 years is 2400 ppb. The EECs for

groundwater (SCI-GROW) were less than the acute DWLOC's, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The GENEEC EEC was 69 ppb, while the estimated groundwater EEC was 0.006 ppb.

Chronic aggregate risk estimates do not exceed HED's level of concern. The EECs for surface water (GENEEC) were less than the chronic DWLOCs, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The EECs for groundwater (SCI-GROW) were less than the chronic DWLOC's, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The GENEEC and SCI-GROW EECs were 7.6 and 0.006 ppb, respectively.

Cancer DWLOCs were not calculated because cancer dietary (food) risk was at 1.0 X 10⁻⁶. Exposure to propargite from drinking water derived from groundwater sources is minimal and would not contribute significantly to the cancer risk. Surface water concentrations below 0.2 ppb would result in cancer risks below 1 X 10⁻⁶ for drinking water alone when back calculated. Time weighted average propargite concentration in surface water samples from the USGS NAWQA (Oristimba Creek Watershed) for the years 1992-1993 were 0.30 and 1.24 ppb, respectively. Therefore, even when monitoring data are used cancer exposure to propargite from surface water sources is greater than HED's level of concern.

cc : Chem F, Chron F. Morton

RDI:Team (1/6/00); RARC (2/1/00); SVH:6/6/00

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2.0 PHYSICAL/CHEMICAL PROPERTIES CHARACTERIZATION DESCRIPTION OF CHEMICAL

Propargite [2-(p-tert-butylphenoxy)cyclohexyl-2-propynyl sulfite] is a non-systemic organosulfite acaricide.

Comite

Trade Name: Omite,

Empirical Formula: $C_{19}H_{26}O_4S$ Molecular Weight: 350.5 g/mole CAS Registry No.: 2312-35-8PC Code: 097601

IDENTIFICATION OF ACTIVE INGREDIENT

Propargite technical is a light to dark brown viscous liquid which decomposes (~200° C) before boiling, has a specific gravity of 1.10 at 20° C, octanol/water partition coefficient (log K_{ow}) of 5.8 at 25° C, and vapor pressure of 4.49 x 10⁻⁹ mm Hg at 25° C. Propargite is only slightly soluble in water (1.9 ppm at 25° C), but is soluble in most organic solvents (>200 g/L in acetone, dichloromethane, hexane, methanol, and toluene).

3.0 HAZARD CHARACTERIZATION

Table 1. Summary of Toxicology Endpoint Selection.

Tubic I. Builling	or romeology i	Enupoint Selection.						
EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY TYPE/ MRID					
Acute Dietary- females 13-50	NOAEL= 8 UF = 100 FQPA = 1	Increased incidence of fused sternebrae in fetuses at 10 mg/kg/day (LOAEL).	Developmental Toxicity in Rabbits 41336301					
Acute Dietary- general population	NOAEL = N/A $UF = N/A$ $FQPA = 1$	No relevant single exposure endpoint was identified.	N/A					
Acute RfD (females 13-50) = 0.08 mg/kg/day Acute RfD (Gen. Pop.) = N/A aPAD = 0.08 mg/kg/day								
Chronic Dietary	NOAEL = 4 UF = 100 FQPA = 1	Decreased body weight/body weight gain and increased mortality at 19 mg/kg/day(LOAEL) for males.	Chronic Feeding and Carcinogenicity in Rats 41750901					
		Chronic RfD = 0.04 mg/kg/day cPAD = 0.04 mg/kg/day						
Cancer Risk		Q_1 * = 2.01 X 10 ⁻¹ (mg/kg/day) ⁻¹						
Short-Term ¹ (Dermal)	NOAEL= 6 MOE = 100	Decreased maternal body weight gain at 8 mg/kg/day (LOAEL).	Developmental Toxicity in Rabbits 41336301					
Intermediate-Term ¹ (Dermal)	NOAEL= 4 MOE = 100	Reduction in body weight gain and food consumption at 20 mg/kg/day (parental LOAEL).	Reproductive Toxicity in Rats 41352401					
Long-Term ¹ (Dermal)	NOAEL= 4 MOE = 100	Decreased body weight / body weight gain and increased mortality at 20 mg/kg/day (LOAEL).	Chronic Feeding and Carcinogenicity in Rats 41750901					
Short Term ² (Inhalation)								
Intermediate Term ² (Inhalation)	LOAEL= 0.31mg/L or 50 mg/kg	Increased mortality at 0.31 mg/L (LOAEL) in males.	Acute Inhalation in Rats 42857003					
Long Term ² (Inhalation)	MOE = 1000							

Propargite is considered corrosive and has been placed in Category I for both eye and dermal irritation in rabbits. There have also been documented reports of dermal and eye irritation developing in workers exposed to propargite in the field. Evidence for its dermal sensitization potential have been noted; a study that provides conclusive results has not been possible due to the irritating properties of this chemical.

¹ A 14% dermal absorption factor will be used for risk assessment and an MOE of 100.
² An MOE of 1000 was selected for inhalation, including a 10X factor due to lack of a NOAEL, severity of effects at the lowest dose tested, hour duration.

In a rabbit developmental toxicity study, propargite formulated as Omite (85% a.i.) was administered in corn oil by gavage to New Zealand White rabbits, 25 per dose, at levels of 0, 2, 4, 6, 8, or 10 mg/kg/day) on gestation days (GD) 7-19. A reduction in maternal body weight gain occurred at doses of 8 and 10 mg/kg/day during GD 7-20 (gain of 9 g and loss of 20 g, respectively, versus a gain of 114, 165 and 119 g for control, 2 and 4 mg/kg/day, respectively). Only the incidence of fetuses with fused sternebrae at 10 mg/kg/day was considered to be significantly greater than that observed in concurrent and historical controls. The maternal LOAEL is 8 mg/kg/day, based on decreased body weight gain. The maternal NOAEL is 6 mg/kg/day. The developmental LOAEL is 10 mg/kg/day, based on increased incidence of fused sternebrae. The developmental NOAEL is 8 mg/kg/day.

In a chronic toxicity/carcinogenicity study, propargite formulated as Omite (87.2%, a.i.) was administered to 50 Sprague-Dawley Crl:CD BR rats/sex/dose (an additional 10 rats/sex/dose were sacrifice at 53 weeks) in 0.5% corn oil in the diet at dose levels of 0, 50, 80, 400 and 800 ppm (0, 2, 4, 19 and 39 mg/kg/day for males and 0, 3, 5, 24 and 49 mg/kg/day for females) for 24 months. Mortality for males (8/50 and 20/50 at 400 and 800 ppm, respectively) and for females (7/50 at 800 ppm) appeared to be related to the increased incidence of undifferentiated sarcoma in the GI tract. There were dose-related increases in incidence of jejunum tumors in both sexes. The incidences were 0, 0, 0, 10 and 15 tumors (0, 0, 0,17% and 25%) in males and 0, 1, 0, 1, and 9 tumors (0, 2%, 0, 2% and 15%) in females for the control, 50, 80, 400, and 800 ppm dose groups, respectively (60 animals per group). They were not always associated with any increase in ulceration or other signs of irritation of the stomach or jejunum. Tumors of the jejunum were seen in males and females receiving the highest doses of 400 and 800 ppm. The dosing was considered to be adequate to assess the carcinogenic potential of propargite. The LOAEL is 400 ppm (19 mg/kg/day) for males due to increased mortality, decreased body weight and body weight gain, as well as decreases in total protein and calcium. The NOAEL is 80 ppm (4 mg/kg/day) for males. The LOAEL is 800 ppm (39 mg/kg/day) for females due to decreases in body weight and body weight gain. The NOAEL is 400 ppm (24 mg/kg/day) for females.

Propargite did not cause reproductive effects in rats but produced decreased parental and pup body weights. In a two-generation reproduction study, Omite (87.2 % a.i.) was administered to 25 Crl:CDBR rats/sex/dose in their diet at dose levels of 0, 80, 400, and 800 ppm (0, 4, 20, and 40 mg/kg/day) for 10 weeks then mated to produce the F_1 a generation. They were mated a second time after a 2-week rest period to produce the F_1 b generation. The F_1 b generation were treated in a similar manner to produce the F_2 a and F_2 b generation. No compound-related clinical signs or reactions were observed for either parental group. A transient decrease in body weight gain occurred for animals in the high-dose and mid-dose groups. Both food consumption and food efficiency were reduced at 400 and 800 ppm. Necropsy revealed no compound related effects on gross or microscopic histological findings. There were no compound related adverse effects on the reproductive performance of any group. At the high-dose, there were decreases in mean pup weight at birth and during the period of lactation. The systemic LOAEL is 400 ppm (20 mg/kg/day), based on decreased parental body weight gain, and food consumption. The systemic NOAEL is 80 ppm (4 mg/kg/day).

based on reduction of pup weight during lactation. The offspring NOAEL is 400 ppm (20 mg/kg/day). The reproductive LOAEL and NOAEL are > 800 ppm (40 mg/kg/day).

In an acute inhalation toxicity study (MRID 42857003), CD Crl:CD BR rats (5/sex/dose) were exposed by inhalation route (nose only) to propargite (85%, a.i.) at concentrations of 0.31, 0.80, and 1.3 mg/L for 4 hours. Mortality at the lowest level was observed within 24 hours of exposure (1/10). At the 0.80 mg/L dose, deaths occurred on day 2 and 3 (2/10). At the 0.31 mg/L dose, animals recovered and were sacrificed at day 15, the animals at 0.80 mg/L were observed an additional week and showed incomplete recovery. At 1.3 mg/L, all animals (10/10) died between days 2 and 17. Signs of toxicity included labored respiration, decreased activity, nasal discharge, anogenital staining, matted coats, at all levels. The animals at 0.80 and 1.3 mg/L showed moist rales, grasping, perioral encrustation as well. Weight loss was observed in all animals; however, the survivors exceeded their pretest weights at termination. Necropsy revealed discoloration of the lungs. Some showed signs of gastrointestinal distress and discoloration of the skin.

3.2 FQPA Considerations

The FQPA Safety Factor Committee met on August 9,1999 to evaluate hazard and exposure data for propargite and recommend application of the FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996), to ensure the protection of infants and children from exposure to propargite. Based on the lack of increased susceptibility following *in utero* exposure to rats and rabbits and pre/post natal exposure to rats, adequacy of the database, no currently registered residential uses, and because the exposure assessments will not underestimate the potential dietary (food and drinking water) exposures for infants and children from the use of propargite, the FQPA committee recommended reduction of the FQPA Safety Factor to 1X.

3.3 Endocrine Disruption

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the Federal Register of December 28, 1998 (63 FR71541). The Program uses a tiered approach and anticipates issuing a Priority List of chemicals and mixtures for Tier 1 screening in the year 2000. As the Agency proceeds with implementation of this program, further testing of propargite and its end-use products for endocrine effects may be required.

4.0 EXPOSURE ASSESSMENT

4.1 Summary of Registered Uses

Propargite is currently registered for ornamentals and a variety of field, fruit, and vegetable crops. Registered propargite end-use products include emulsifiable concentrate (EC) and wettable powder (WP) formulations. Depending on the crops, these formulations may be applied as broadcast, banded or directed spray or chemigation foliar treatments pre- or postharvest using ground or aerial equipment. Single application rates range from 0.8 to 4.5 pounds per acre. Preharvest intervals range from 7 to 60 days.

Manufacturing-Use Products

A search of the Reference Files System (REFS) conducted 12/16/99 identified a single propargite manufacturing-use product (MP) registered under PC Code 097601: the Uniroyal Chemical Company Inc. 90.6% T (EPA Reg. No. 400-95). Only the 90.6% T is subject to a reregistration eligibility decision.

According to a REFS search, conducted on 12/16/99, there are seven active end-use products (EPs) registered under FIFRA Section 3. These EPs, including the associated Special Local Need (SLN) registrations under FIFRA Section 24(c), are listed in Table 2. For the purpose of generating this Reregistration Eligibility Document (RED), the Agency examined the registered food/feed use patterns and reevaluated the available residue chemistry database for adequacy in supporting these use patterns, based on the product labels registered to Uniroyal Chemical Company.

Table 2. Propargite EPs with Food/Feed Uses Registered to Uniroyal Chemical Company

<u> </u>	C		
on Product Name	Formulation	Label Acceptance Date ¹	EPA Reg. No.
Omite® - 30W Agricultural Miticide	32% WP	7/9/99	400-82 2
C Omite® - 6E Agricultural Miticide	6 lb/gal EC	5/28/98	400-89
EC Comite® Agricultural Miticide	6.55 lb/gal EC	1/14/98 (3/98 in REFs)	400-104 ³
C Comite® II Agricultural Miticide	6 lb/gal EC	1/14/98	400-154 4
Omite® - CR Agricultural Miticide (For California Only)	32% WP	5/27/98	400-425
Omite® - CR Agricultural Miticide (Not For California)	32% WP	5/28/98	400-426 5
Omite® - 30WS Agricultural Miticide	32% WP	7/9/99	400-427

Date of the most recently EPA-approved label found by reviewer in the product jacket or Pesticide Product Label System (PPLS) unless specified otherwise.

4.2 Food Exposure

The directions for use that were considered in the risk assessment are indicated in the Chemistry Chapter (J. Stokes, 1/20/00, D250257). Label revisions are needed. In addition, per Table 1 of OPPTS GLN 860.1000, the feeding restriction on cotton trash (presumably meaning cotton gin byproducts) is not practical. Once adequate residue data are submitted for cotton gin byproducts and a tolerance established, this feeding restriction should be deleted from the label.

The nature of the residue in plants and animals is adequately understood. The HED Metabolism Assessment Review Committee (MARC) concluded the residue of concern in plants and animals is propargite *per se* but required additional data on the metabolism of the propynyl sulfite side chain (N. Dodd, D256182, 6/7/99). The registrant submitted additional data on the metabolism of the propynyl sulfite side chain in rats and this study was classified as acceptable and propynyl sulfite metabolites should not be included as residues of concern (S. Shallal, D259994, 11/4/99). Approximately 56-65 % of the administered dose was eliminated via urine and/or feces within the first 24 hours. Only 2-2.6% of the administered dose was recovered from the carcasses of rats and mice; individual organs were, therefore, not analyzed for radioactivity. Six major metabolites were isolated from rat urine. The proposed metabolic pathway suggests that following the

² Including SLN No. CA810088 (avocado) and CA860070 (orange, grapefruit).

Including SLN Nos. AL910005, AR830015, AZ810022, AZ970004, CA780167, CA820083, CA8300024, CA920011, CA940031, GA910003, ID770005, ID910015, ID940011, ID960016, ID970015, IN990002, MS830024, MT890010, MT900001, NC910007, NV870009, NV880007, OR770013, OR790034, OR910019, OR940012, OR940013, OR970012, SC910003, TX830028, UT790015, UT960006, VA910006, WA770012, WA870029, WA890020, WA910033, WA970010, WI990016, and WY960001.

⁴ Including SLN Nos. CO940006, KS950001, NM940001, TX940005, and TX940006.

⁵ Including SLN Nos. ID950014, OR940021, and WA940007.

cleavage of the 2-propynyl sulfite side chain of the propargite molecule, it is further detoxified via glutathione conjugation with further degradation leading to formation of the major metabolites.

Analytical methods available for enforcing propargite tolerances include Methods II, V, and VI for plant commodities and Methods III and IV for animal commodities in PAM, Volume II (Sec. 180.259). The preferred enforcement analytical method for plant commodities is Method V. All are gas liquid chromatography (GLC) methods with either sulfur-specific microcoulometric detection (Method II), microcoulometric detection (Method III), or flame photometric detection (Methods IV, V, and VI). Limits of quantitation are 0.08 (milk) and 0.1 ppm (plant and animal commodities).

In frozen storage, propargite is stable in/on avocados for 422 days, corn for 366 days, strawberries for 236 days, dried hops, apples, oranges, and sorghum grain for one year, and in plucked tea leaves, dried green tea, and dried black tea for 259 days. Additional confirmatory storage stability data are required for an oily commodity to support residue studies on peanut and walnut, and storage stability data are required to support corn and peanut processing studies. Propargite is stable in frozen storage for 90 days in milk, beef liver and beef fat, eggs, and chicken fat, and 180 days in beef kidney. Residues were stable for 30 days in beef muscle and declined by 17% after 90 days and 39% after 180 days.

Adequate field trials are available pending submission of required storage stability data, sample storage information, or required label amendments. Data on oranges indicate that residues up to 8.3 ppm may occur from registered use and that the 5 ppm tolerance is inadequate. This tolerance has been reassessed at 10 ppm. In sorghum grain, maximum propargite residues were 3.8 ppm, supporting a decrease in the current 10 ppm tolerance. Although one sample of cottonseed showed a residue of 0.11 ppm, based on the residue data for other samples after treatment at higher rates, HED considers the existing 0.1 ppm tolerance adequate to cover the current label use. This 0.1 ppm tolerance is in harmony with Codex. For all other crops the residue data support the established tolerances. Additional field trials are needed on cotton to determine a tolerance for propargite residues in/on cotton gin byproducts.

Adequate processing studies have been submitted for potatoes, citrus, field corn, grapes and peanuts. Storage stability data are required to support the corn and peanut processing studies. The corn processing study indicated that a tolerance is required for residues in aspirated grain fractions. The citrus processing study did not detect residue concentration in dried pulp, indicating that the current 40 ppm tolerance should be revoked. Residues concentrated in orange oil by 7x; based on a HAFT of 4 ppm (residue range 1.6-8.3 ppm; n=6) in oranges, a tolerance of 30 ppm is required. Although residues concentrated in raisins by 1.7x, this factor applied to the HAFT of 4.7 ppm yields a concentration in raisins of 8 ppm, which is lower than the 10 ppm tolerance for residues in/on the RAC. Therefore, a tolerance for raisins is not required.

The reregistration requirements for animal feeding studies are fulfilled. Acceptable ruminant and poultry feeding studies have been submitted and evaluated. In cows dosed with propargite at 50

ppm (approximately 2x) residues of propargite *per se* were <0.01-0.011 ppm in milk, 0.086-0.2 ppm in fat, and <0.01-0.02 ppm in liver, muscle, and kidney. In a poultry feeding study, propargite residues were <0.01 ppm (nondetectable) in eggs from hens dosed at 5, 15, or 50 ppm (1, 3, and 10x). Propargite residues in fat were <0.01 ppm in hens dosed at 5 ppm and 0.013-0.082 ppm in from hens dosed at 15 or 50 ppm. Propargite was not analyzed in tissues. In the poultry metabolism study, the parent compound was not detected in muscle, liver, or kidney.

The metabolism of propargite in rotated crops is similar to that in primary crops. Based on adequate confined and limited field rotational crop studies, the Agency concluded that a sixmonth plantback interval (PBI) for root crops and a two-month PBI for all other crops are acceptable (J. Stokes, 5/31/00, D230867).

4.2.1 Tolerance Reassessment Summary

Effective 10/19/99 EPA has revoked the following tolerances: propargite residues in/on apples, apricots, succulent beans, cranberries, figs, peaches, pears, plums, and strawberries [established under §180.259(a)] and dried figs (§186.5000) [FR 64 39068-39072, 7/21/99]. Uses of propargite on these crops have been canceled for over 3 years. The final rule will remove §186.5000, transferring the tolerances for residues in hops, dried and tea, dried to §180.259.

4.2.2 Codex Harmonization

The U.S. tolerances for propargite residues and Codex MRLs are identical with respect to the residue regulated; both are defined as the parent compound. A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in the propargite product and residue chemistry chapter.

4.2.3 Dietary Exposure Reassessment

Consumption Data

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEMTM), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. For acute dietary risk assessments, the entire distribution of single day food consumption events is combined with either a single residue level (deterministic analysis, risk at 95th percentile of exposure reported) or a distribution of residues (probabilistic analysis, referred to as "Monte Carlo," risk at 99.9th percentile of exposure reported) to obtain a distribution of exposure in mg/kg/day. For chronic dietary risk assessments, the three-day average of consumption for each sub-population is combined with residues in commodities to determine average exposure in mg/kg/day.

Propargite Residue Data

Revised anticipated residues (ARs) (T. Morton, D266001, 5/24/00) were calculated and used in

the revised dietary exposure analyses. The Biological and Economic Analysis Division (OPP/BEAD) has provided usage information for propargite (Jihad Alsadek, 5/22/00). Field trial data and USDA Pesticide Data Program (PDP) data were used in calculation of ARs. For all PDP analyses the ½ Limit of Detection (LOD) value was a weighted average of all laboratory limits of detection.

4.2.4 Acute Dietary Exposure Assessment

Estimated acute dietary exposure is below HED's level of concern for the U.S. Population and all subpopulations at the 99.9th percentile. Use of PDP monitoring data, field trial data, and calculated livestock ARs results in a risk estimate of 2 % of the acute PAD (% aPAD) for the subpopulation Females (13-50 years) at the 99.9th percentile.

Table 3. Population Adjusted Dose Acute Dietary Exposure Results for Propargite (PAD = 0.08 mg/kg/day).

Subgroups	95 th Percentile Exposure mg/kg/day (%aPAD)	99 th Percentile Exposure mg/kg/day (%aPAD)	99.9 th Percentile Exposure mg/kg/day (%aPAD)		
Females (13-50 yrs)	0.00005	0.0001	0.001		
	(<1%)	(<1%)	(2%)		

4.2.5 Chronic Dietary Exposure Assessment

Estimated chronic dietary exposure is below HED's level of concern. Use of PDP monitoring data, field trial data, and calculated livestock ARs results in a maximum risk of <1 % of the chronic PAD (% cPAD) for the U.S. Population and all subpopulations.

Table 4. Propargite Chronic Dietary Exposure/Risk.

	Chronic					
Population Subgroup	Exposure (mg/kg/day)	% cPAD				
U.S. Population	0.00001	<1				
All infants (<1 yr)	0.00001	<1				
Children (1-6 yrs)	0.00001	<1				
Children (7-12 yrs)	0.00001	<1				
Females (13-50 years)	0.00001	<1				
Males (20+ yrs)	0.00001	<1				

4.2.6 Cancer Dietary Exposure Assessment

The cancer dietary risk estimate for propargite is 1.2×10^{-6} . Results of the analyses indicate potential residues in milk contribute to estimated exposure and risk. There were no detections of propargite in PDP data for milk and the highest residue in the 2x feeding study was at the 0.011 ppm. Therefore, a sensitivity analysis was performed by inserting zeroes for the milk commodities resulting in a cancer dietary risk estimate of 1.0×10^{-6} .

Table 5. Propargite Cancer Dietary Exposure/Risk.

	Ca	ancer	Cancer (with zeroes inserted for milk commodities)			
Population Subgroup	Exposure (mg/kg/day)	Lifetime Risk $(Q_1^* = .201)$	Exposure (mg/kg/day)	Lifetime Risk $(Q_1^* = .201)$		
U.S. Population	0.000006	1.2 X 10 ⁻⁶	0.000005	1.0 X 10 ⁻⁶		

4.2.7 Drinking Water Exposure

Environmental Fate and Effects Division (EFED) provided HED with estimated environmental concentrations (EECs) for propargite in surface water and groundwater. EFED model estimates include two applications of propargite. GENEEC and SCI-GROW EECs are as follows:

Table 6. GENEEC and SCI-GROW EECs (ug/L) for propargite use.

Model	EECs
Surface Water (GENEEC)	Walnuts Peak = 69.01 ppb Average 56 day = 7.6 ppb*
Groundwater (SCI-GROW)	0.006 ppb

^{*} Value reported by EFED was 22.8 ppb, current HED policy states that the average 56 day GENEEC value should be divided by 3 for chronic DWLOC calculation

In addition, EFED provided time weighted averages for propargite concentrations in surface water samples from the USGS NAWQA (Oristimba Creek Watershed) for the years 1992 and 1993 were 0.30 and 1.24 ppb, respectively.

4.2.7.1 DWLOCs for Acute Exposure

Acute DWLOCs were calculated based on the acute dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the acute DWLOCs, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The acute DWLOC for Females 13-50 years is 2300 ppb. The GENEEC surface water value is 69 ppb.

The EECs for groundwater (SCI-GROW) were less than the acute DWLOC's, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The Agency's default body weights and water consumption values used to calculate DWLOCs are

as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). To calculate the DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation:

where acute water exposure (mg/kg/day) = [aPAD - (acute food <math>(mg/kg/day)]

Table 7. Drinking Water Levels of Comparison for Acute Dietary Exposure.

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	DWLOC _{acute} (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
Females 13-50 yrs.	0.08	0.001	0.08	2400	69	0.006

4.2.7.2 DWLOCs for Chronic Exposure

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the chronic DWLOCs, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The EECs for groundwater (SCI-GROW) were less than the chronic DWLOC's, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). To calculate the chronic DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD using the equation:

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day))]

Table 8. Drinking Water Levels of Comparison for Chronic Dietary Exposure.

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	DWLOC _{chronic} (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
US Population	0.04	0.00001	0.00001 0.04		7.6	0.006
All Infants	0.04	0.00001	0.04	400	7.6	0.006
Children 1-6	0.04	0.00001	0.04	400	7.6	0.006
Children 7-12	0.04	0.00001	0.04	0.04 400		0.006
Females 13-50 yrs.	0.04	0.00001	0.04	1200	7.6	0.006
Males 20+ yrs	0.04	0.00001	0.04	1400	7.6	0.006

4.2.7.3 DWLOCs for Cancer Exposure

Cancer DWLOCs were not calculated because cancer dietary (food) risk was at 1.0 X 10⁻⁶. Exposure to propargite from drinking water derived from groundwater sources is minimal and would not contribute significantly to the cancer risk. Surface water concentrations below 0.2 ppb would result in cancer risks below 1 X 10⁻⁶ for drinking water alone when back calculated. Time weighted average propargite concentration in surface water samples from the USGS NAWQA (Oristimba Creek Watershed) for the years 1992-1993 were 0.30 and 1.24 ppb, respectively. Therefore, even when monitoring data are used cancer exposure to propargite from surface water sources is greater than HED's level of concern.

4.3 Non-Dietary Exposure

4.3.1 Occupational Handler Exposure Scenarios

EPA has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with propargite. Based on the use patterns and potential exposures described above, 14 major agricultural exposure scenarios are identified in this document to represent the extent of propargite uses.

Agricultural exposure scenarios include: (1a) mixing/loading liquids for aerial application, (1b) mixing/loading liquids for chemigation, (1c) mixing/loading liquids for groundboom application, (1d) mixing/loading liquids for orchard airblast sprayer application, (1e) mixing/loading liquids for application of high pressure handwand, (2a) mixing/loading wettable powder for aerial application, (2b) mixing/loading wettable powder for groundboom application, (2c) mixing/loading wettable powder for orchard airblast sprayer application, (2d) mixing/loading wettable powder for application of high pressure handwand, (3) applying sprays with fixed-wing aircraft, (4) applying sprays using a groundboom sprayer, (5) applying sprays with an airblast sprayer, (6) applying liquids with a high pressure handwand and (7) flagging during aerial spray application.

In most cases, HED assesses the exposure and risk to mixer/loaders and applicators separately for tractor drawn applications (i.e., airblast, groundboom, and granular spreaders). This practice has evolved, not because it is believed that there are always separate job functions, but rather because of the limited amount of information regarding these practices along with limited exposure data.

HED has adopted a methodology to present the risks separately for some scenarios and combine others. Most of the hand- held equipment such as backpack sprayers, and push type granular spreaders are assessed as a combined function. With these types of small operations the mixing, loading, and applying are almost always carried out by the same individual and there are data available to estimate exposure from these activities. For equipment such as fixed-wing-aircraft, groundboom tractors, and airblast sprayers the applications are assessed separately from the individual who mixes and loads the formulated product. HED assumes that the pilots are rarely involved in the mixing/loading. By separating the two job functions, HED can determine the most appropriate PPE or engineering control without requiring the handler to wear PPE throughout the entire workday or engineering controls that are not needed.

The potential handler exposures are assessed using the toxicological endpoints and uncertainty factors associated with the active ingredient. Therefore, the PPE and engineering controls are determined by the assessment of the active ingredient and not the currently required risk mitigation measures on propargite labels. This distinction of determining risk mitigation measures based on the active ingredient instead of the label required PPE is also important because of the nature of the end-use products. For example, some end-use products require additional PPE that are not necessary for the active ingredient because of the end-use product's potential for eye and/or skin irritation based on inerts. Conversely, the Agency does not want to mandate additional PPE (e.g., heat stress issues) if it is not required based on the endpoint and uncertainty factors. Baseline attire (long pants, long sleeved shirt, and no gloves) is not presented in this chapter because of the need for additional PPE and/or engineering controls for all scenarios. There are some PPE, such as chemical-resistant aprons and/or head gear, that the Agency uses as qualitative measures because there are no recognized protection factors (PF) to assess their effectiveness.

4.3.1.1 Occupational Handler Exposure Data Sources and Assumptions

Uniroyal submitted applicator exposure studies in support of the reregistration process for

propargite. Theses studies include:

Airblast applicator exposure studies (MRID Nos. 418486-05 and 420997-02) Groundboom applicator exposure study (MRID No. 418486-05)

It is HED's policy to combine chemical-specific studies with similar surrogate data from the Pesticide Handlers Exposure Database (PHED) to assess handler exposures for regulatory actions. In addition, the exposure estimates from PHED (V1.1) are used to assess exposure where no chemical specific data are available.

Table 9. Exposure Variables for Agricultural Uses of Propargite.

Exposure Scenario (Scenario #)	Are Chemical Specific Monitoring Data Available? ^a	Application Rates (lb ai/acre) ^b	Daily Acres Treated ^c
	Mi	xer/Loader Exposure	
Mixing/Loading Liquids for Aerial Application (1a)	No	1.5 min / 2.5 max carrot, sugar beet, potatoes, dry beans, mint, corn (field, pop, sweet), sorghum grain, alfalfa, clover, peanut, jojoba	350
		2.5 grapefruit, orange	125
		4.5 almond, walnut	
		1.6 cotton	350-1200
		hops max 2.5	80
Mixing/Loading Liquids for Chemigation (1b)	No	2.0 min /2.5 max Potatoes, corn (sweet)	350
Mixing/Loading Liquids for Groundboom Application (1c)	No	1.5 min /2.5 max potatoes, corn (field, pop, sweet) sorghum grain, alfalfa, clover, cotton, peanut, jojoba and mint	80
		2.5 hops	40
Mixing/Loading Liquids for Airblast Sprayer Application (1d)	No	1.5 quince, cherry, prunes, orange, grapefruit, lemon, lime, tangerine, boysenberry, current, raspberry, hops, date, persimmons,	40
		2.5 Xmas tree plantations, conifers, shade trees	40
		1.5 min/max 3.0 almond, filbert, macadamia nut, pecan, pistachio	40
		4.5 walnut	40
Mixing/Loading Liquids for Application of High Pressure Handwand (1e)	No	1.5 non-bearing nursery stock	5
Mixing/Loading Wettable Powder for	No	3.0 nectarine	125
Aerial Application (2a)		4.0 walnut	125

Exposure Scenario (Scenario #)	Are Chemical Specific Monitoring Data Available? ^a	Application Rates (lb ai/acre) ^b	Daily Acres Treated ^c	
Mixing/Loading Wettable Powder for Groundboom Application (2b)	No	1.6 peanut	80	
Mixing/ Loading Wettable Powder for Airblast	No	4.5 max grapefruit, orange, lemon, avocado	40	
Sprayer Application (2c)		3.0 grapes	40	
Mixing/ Loading Wettable Powder for Application of High Pressure Handwand (2d)	No	0.5 min / 2.5 max non-bearing nursery stock	5	
	A	Applicator Exposure		
Applying Sprays with Fixed-Wing Aircraft –Enclosed Cockpit (3)	No	1.5 min / 2.5 max carrot, sugar beet, potatoes, dry beans, mint, corn (field, pop, sweet), sorghum grain, alfalfa, clover,	350	
		2.5 grapefruit, orange	125	
		4.5 almond, walnut		
		1.5 peanut, jojoba	125	
		1.6 cotton	350-1200	
		hops max 2.5	80	
Applying Sprays with a Groundboom Sprayer (4)	Yes 41848606	1.5 min / 2.5 max potatoes, corn (field, pop, sweet) sorghum grain, alfalfa, clover, cotton, peanut, jojoba and mint	80	
Applying Sprays with an Airblast Sprayer (5)	Yes 41848605 42099702	1.5 min quince, cherry, prunes, orange, grapefruit, lemon, lime, tangerine, boysenberry, current, raspberry, hops, date, persimmons,	40	
		2.5 Christmas tree plantations, conifers, shade trees	40	
		1.5min / max 3.0 almond, filbert, macadamia nut, pecan, pistachio	40	
		4.5 walnut	40	
Applying Liquids with a High Pressure Handwand (6)	No	0.5 min / 2.5max non-bearing nursery stock	5	
		Flagger Exposure		
Flagging During Aerial Spray Application (7)	No	1.5 min / 2.5 max carrot, sugar beet, potatoes, dry beans, mint, corn (field, pop, sweet), sorghum grain, alfalfa, clover, peanut, jojoba	350	
		2.5 grapefruit, orange	125	
		4.5 almond, walnut		
		1.6 cotton	350-1200	

Exposure Scenario (Scenario #)	Are Chemical Specific Monitoring Data Available? ^a	Application Rates (lb ai/acre) ^b	Daily Acres Treated ^c
		2.5 max hops	80

^a Available chemical-specific passive dosimetry data have been combined with PHED (V1.1).

The handler exposure assessments encompass all of the major uses of propargite throughout the country. It is difficult to assess all of the "typical" agricultural uses (i.e., actual or predominant application rates and farm sizes), and therefore, an assessment has been developed that is believed to be realistic and yet provides a reasonable certainty that the exposures are not underestimated. The assumptions and uncertainties are identified below to be used in risk management decisions:

- Application Rates: The application rates are the maximum allowable that were identified on the available product labels. A range of application rates were used when the maximum application rates for various crops varied widely. Application rates have been rounded off.
- Amount Handled: The daily acres treated are HED standard values (see Table 9). Deviations from these standard values include the aerial acreage for orchard fruits, tree nuts, and Christmas trees. The orchard acreage is assessed at 125 acres because fruit orchards are grown in smaller plots, and cotton field is assessed at 350 to 1200 acres.
- *Unit Exposures:* The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A, Table A4 of the Occupational Exposure Chapter, D266207, S. Tadayon, 6/6/00. While data from PHED provides the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.
- BEAD provided data for both commercial applicator and private grower; therefore, calculations were performed for both, where applicable. Two exposure frequencies were used in the calculations, the first represented the maximum number of applications per site per season to represent private use (7), and the second frequency applied a factor of two to the first frequency to represent commercial handlers making multiple applications per site per season (14).

^b Application rates are the maximum or range found on EPA Reg. Nos. 400-82, 400-83, 400-89, 400-104, 400-154, 400-425, 400-426, 400-427.

^c Daily acres treated are based on HED's estimates of acreage that would be reasonably expected to be treated in a single day for each exposure scenario of concern.

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of risk mitigation (PPE and engineering controls) to achieve a margin of exposure of 100 for dermal exposure and 1,000 for inhalation exposure or cancer risk of 1.0E-4. Appendix A presents the short-term and intermediate term MOE calculations for baseline exposure plus the risk mitigation measures of personal protective equipment (PPE) and engineering controls using the passive dosimetry results from the chemical-specific studies combined with surrogate data from PHED for the agricultural uses of propargite. Table 10 presents the cancer risk calculations for baseline exposure plus the risk mitigation measures of personal protective equipment (PPE) and engineering controls.

EPA calculated the baseline MOE (short-term and intermediate-term) and cancer for each of the exposure scenarios using the following **baseline** PPE assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots);
- occupational mixers and loaders using open mixing techniques are wearing long-sleeved shirts, long pants, and no gloves;
- occupational applicators who use open cab airblast or tractor-driven application equipment and handlers flagging for aerial applications are wearing long-sleeved shirts, long pants, and no gloves; and
- occupational handlers (mixers, loaders, and applicators) who use hand-held application equipment are wearing long-sleeve shirts, long pants, and no gloves.

If the baseline short-term or intermediate-term MOE calculated using this baseline PPE was 100 or greater (since the NOAEL is based on data from animal studies) for an exposure scenario, then no further calculations were made. If the baseline short-term or intermediate-term MOE was less than 100 for any exposure scenario, an additional short-term or intermediate-term MOE was calculated based on increasing the level of PPE over the baseline PPE. HED calculated the additional PPE short-term or intermediate-term MOE for each occupational exposure scenario with a baseline total MOE of less than 100, using the following additional <u>PPE</u> assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots);
- occupational mixers and loaders using open mixing techniques are wearing long-sleeved shirts and long pants and gloves;
- occupational applicators who use open cab airblast or tractor-driven application equipment and handlers flagging for aerial applications are wearing (except flaggers- no gloves) longsleeved shirts and long pants;

• Also, if necessary, a dust/mist mask represented by a 10-fold protection factor is added to mitigate the risks.

If the additional-PPE short-term or intermediate-term MOE calculated using this additional-PPE was 100 or greater (the NOAEL is based on data from animal studies) for an exposure scenario, then no further calculations were made. If the additional-PPE short-term or intermediate-term MOE remained less than 100 for any occupational exposure scenario, an addition short-term or intermediate-term MOE was calculated based on mandatory use of engineering controls where feasible. Engineering controls are not available for occupational handlers (mixers, loaders, and applicators) who use hand-held application equipment. HED calculated the engineering-control short-term or intermediate-term MOE for each occupational exposure scenario with an additional-PPE short-term or intermediate-term MOE of less than 100, using the following engineering control assumptions:

- all occupational handlers are wearing footwear (socks plus shoes or boots);
- occupational mixers and loaders handling liquid formulations using a closed system are wearing chemical-resistant gloves plus long-sleeved shirts and long pants;
- occupational mixers and loaders handling wettable powders using a closed system (watersoluble packages) are wearing long-sleeved shirts and long pants, and chemical-resistant gloves; and
- occupational applicators who use aerial, airblast, or tractor-driven application equipment and handlers flagging for aerial applications are located in enclosed cabs or cockpits and are wearing long-sleeved shirts and long pants, and no gloves.

4.3.1.2 Occupational Handler Risk Characterization

Table 13 summarizes the numeric MOE values for both the short- and intermediate-term exposure durations as well as cancer risk estimates. In the majority of cases, it is dermal exposure rather than the inhalation exposure contributing the most to the exposure estimate (dermal and inhalation exposures were not combined). The MOEs are presented for baseline, PPE and engineering controls. Cancer risk estimates are also summarized at different levels of mitigation. Baseline represents long pants, long-sleeved shirts and no gloves; PPE represents exposure while wearing long pants, long-sleeved shirts and chemical resistant gloves, and an organic vapor respirator (10-fold protection factor) while using open mixing/loading systems and open cab tractors. The engineering controls represent exposure while wearing long pants, long-sleeved shirts and no gloves (except chemical resistant gloves for closed loading systems) while using closed mixing/loading systems and enclosed cabs/cockpits.

The results of the **short-term** exposure duration indicate that the MOEs range from less than 1 to 2,570. A total of 71 MOEs were calculated for the various application rates assessed in each

scenario. Based on the maximum level of protection (e.g., various levels of PPE or engineering controls) all MOEs are greater than 100.

The results of the **intermediate-term** exposure duration indicate that the total MOEs range from 1 to 2,000. A total of 70 MOEs were calculated for the various application rates assessed in each scenario. Based on the maximum level of protection (e.g., various levels of PPE or engineering controls) all MOEs are greater than 100.

The baseline cancer risk estimates for handlers ranged from 1.2E-2 to 8.2E-6. When engineering controls were added the cancer risk was mitigated to 1.1E-4 to

Table 10. Exposure Variables, MOEs and Cancer for Agricultural used of Propargite.

Exposure Scenario (Scenario #) Crop Group	Crop Application Rates		Rates Acres		Short-Term Dermal MOEs		Intermediate-Term Dermal MOEs			Inhalation MC		
		(lb ai/acre	(lb ai/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE
	Mixer/Loader Exposure											
Mixing/Loading Liquids for Aerial	Liquids for Aerial Vegetable beet, potatoes,	Min 2.0	350	1	160	NA	<1	125	NA	4135	NA	
Application (1a) Legume Vegetable dry be	dry beans, mint	Max 2.5	x 2.5		130	NA	<1	100	NA	3305	NA	

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates (lb ai/acre)	Daily Acres	Sho	ort-Term I MOEs		Interm	ediate-Term MOEs	n Dermal	Inh	alation M	OEs	Cancer		
			(to al/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
	Herbs & Spices	hops	Max 2.5	80	4	560	NA	3	435	NA	14465	NA	NA	2.2E-3/ 4.4E-3	2.4E-5/ 4.8E-5	7.0E-6/ 1.4E-5
	Citrus Fruits	grapefruit, orange	Max 2.5	125	3	360	NA	2	280	NA	9260	NA	NA	3.4E-3/ 6.8E-3	3.8E-5/ 7.6E-5	1.1E-5/ 2.2E-5
	Tree Nuts	almond, walnut	Min 2.5	125	3	360	NA	2	280	NA	9260	NA	NA	3.4E-3/ 6.8E-3	3.8E-5/ 7.6E-5	1.1E-5/ 2.2E-5
		Max 4.5		2	200	NA	1	155	NA	5145	NA	NA	6.2E-3/ 1.3E-2	6.8E-5/ 1.4E-4	2.0E-5/ 4.0E-5	
	Cereal Grains	corn (field, pop, sweet),	Min 1.5	350	2	215	NA	1	165	NA	5510	NA	NA	5.8E-3/ 1.2E-2	6.4E-5/ 1.3E-4	1.9E-5/ 3.7E-5
	Non-grass Animal Feed	sorghum grain, alfalfa, clover	Max 2.5		1	130	NA	<1	100	NA	3305	NA	NA	9.9E-3/ 2.0E-2	1.1E-4/ 2.1E-4	3.1E-5/ 6.2E-5
	Oil Seed	cotton	Max 1.6	350	2	200	NA	1	155	NA	5165	NA	NA	6.2E-3/ 1.3E-2	6.8E-5/ 1.4E-4	2.0E-5/ 4.0E-5
				1200	<1	60	155	<1	45	120	1505	NA	NA	2.2E-2/ 4.4E-2	2.4E-4/ 4.8E-4	6.8E-5/ 1.4E-4
		peanut, jojoba	Min 1.5	350	2	215	NA	1	165	NA	5510	NA	NA	5.8E-3/ 1.2E-2	6.4E-5/ 1.3E-4	1.9E-5/ 3.7E-5
			Max 2.5		1	130	NA	<1	100	NA	3305	NA	NA	9.9E-3/ 2.0E-2	1.1E-4/ 2.1E-4	3.0E-5/ 6.0E-5
	Ornamental plants	Christmas Tree conifer seed	Max 2.5	125	3	360	NA	2	280	NA	9260	NA	NA	3.4E-3/ 6.8E-3	3.8E-5/ 7.6E-5	1.1E-5/ 2.2E-5
Mixing/Loading Liquids for	Roots and vegetable	potatoes, corn (sweet)	Min 2.0	350	1	160	NA	1	125	NA	4135	NA	NA	7.8E-3/ 1.6E-2	8.4E-5/ 1.7E-4	2.4E-5/ 4.8E-5
Chemigation (1b)	Cereal Grains	1	Max 2.5		1	130	NA	<1	100	NA	3305	NA	NA	9.9E-3/ 2.0E-2	1.1E-4/ 2.1E-4	3.0E-5/ 6.0E-5

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates (lb ai/acre)	Daily Acres	Sho	rt-Term D MOEs	Dermal	Interme	ediate-Term MOEs	Dermal	Inhalation MOEs			Cancer		
			(Ib ai/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
Mixing/Loading Liquids for Groundboom	Roots and Vegetable	potatoes, corn (field, pop, sweet)	Min 1.5	80	7	930	NA	6	725	NA	24110	NA	NA	1.4E-3/ 2.7E-3	1.5E-5/ 2.9E-5	4.2E-6/ 8.4E-6
Application (1c)	Cereal Grains	sorghum grain, alfalfa, clover,														
Non-grass A Feed	Non-grass Animal Feed	cotton, peanut, jojoba and mint														
	Oil Seed Herbs and Spices		Max 2.5		4	560	NA	3	435	NA	14465	NA	NA	2.2E-3/ 4.4E-3	2.4E-5/ 4.8E-5	7.0E-6/ 1.4E-05
														4.42/3	4.6L=3	1.4E-03
Mixing/Loading Liquids for Airblast	Pome Fruits	quince, cherry,	1.5	40	15	1865	NA	10	1450	NA	48220	NA	NA	6.6E-4/ 1.3E-3	7.2E-6/ 1.5E-5	2.2E-6/ 4.4E-6
Sprayer Application (1d)		grapefruit										1.3E-3	1.515-5	4.4E-0		
(Iu)	Citrus Fruits	tangerine, boysenberry, current, date raspberry, hops, persimmons,														
	Berries															
	Herbs and Spices															
	Tropical and Subtropical Fruits															
	Tree Nuts	macadamia	Min 1.5		15	1865	NA	10	1450	NA	48220	NA	NA	6.6E-4/ 1.3E-3	7.2E-4/ 1.5E-5	2.2E-6/ 4.4E-6
		nut, pecan, pistachio	Max 3.0		7	930	NA	6	725	NA	24110	NA	NA	1.4E-3/ 2.7E-3	1.5E-5/ 3.0E-5	4.2E-6/ 8.4E-6
		walnut	Max 4.5		5	620	NA	4	485	NA	16075	NA	NA	2.0E-3/ 4.0E-3	2.2E-5/ 4.4E-5	6.4E-6/ 1.3E-5
	Ornamental plants	Christmas Tree plantation, conifers, shade trees	Max 2.5		9	1120	NA	7	870	NA	28935	NA	NA	1.1E-3/ 2.2E-3	1.2E-5/ 2.5E-5	3.6E-6/ 7.2E-6
Mixing/Loading Liquids for Application of High Pressure Handwand (1e)	Non-bearing nursery stock	all crops	Max 1.5	5	120	NA	NA	90	11595	NA	38578 0	NA	NA	8.5E-5/ 1.7E-4	3.0E-5/ 6.0E-5	4.2E-7/ 8.4E-7

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates	Daily Acres	Sho	rt-Term D MOEs	ermal	Interm	ediate-Term MOEs	Dermal	Inh	alation M	OEs	Cancer		
			(lb ai/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
Mixing/Loading Wettable Powder for Aerial	Stone fruits	nectarine	Max 3.0	125	2	40	325	1	30	255	215	2155	NA	5.8E-3/ 1.2E-2	6.2E-4/ 1.3E-3	3.3E-5/ 6.7E-5
Application (2a)	Tree Nuts	walnut	Max 4.0		1	30	245	1	25	190	160	1615	NA	7.7E-3/ 1.4E-2	8.4E-4/ 1.7E-3	4.2E-5/ 9.7E-5
	Ornamental plants	Christmas Tree	Max 2.5	125	2	50	390	2	40	305	255	2585	NA	4.8E-3/ 9.7E-3	4.1E-4/ 8.3E-4	2.8E-5/ 5.6E-5
Mixing/Loading Wettable Powder for Groundboom Application (2b)	Oil Seed	peanut	Max 1.6	80	5	120	NA	4	90	745	625	6310	NA	2.0E-3/ 4.0E-3	2.4E-4/ 4.8E-4	1.1E-5/ 2.2E-5
Mixing/ Loading Wettable Powder	Citrus fruits	grapefruit, orange, lemon,	Min 3.0	40	6	125	NA	5	100	NA	665	6730	NA	1.9E-3/ 3.7E-3	2.2E-4/ 4.4E-4	1.1E-4/ 2.1E-4
for Airblast Sprayer Application (2c)	Tropical and subtropical fruits	avocado	Max 4.5		4	85	680	3	65	530	445	4485	NA	2.8E-3/ 5.6E-3	3.2E-4/ 6.4E-4	1.6E-5/ 3.2E-5
	Herbs & spices	hops	Min 2.0		9	190	NA	7	145	NA	1000	NA	NA	1.2E-3/ 2.5E-3	1.5E-4/ 2.9E-4	7.0E-6/ 1.4E-5
			Max 2.5		7	150	NA	5	120	NA	800	8075	NA	1.6E-3/ 3.1E-3	1.8E-4/ 3.6E-4	8.8E-6/ 1.8E-5
	Small Fruits	grapes	Max 3.0		6	125	NA	5	100	NA	665	6730	NA	1.9E-3/ 3.7E-3	2.2E-4/ 4.4E-4	1.1E-5/ 2.1E-5
Mixing/ Loading Wettable Powder	Non- bearing Nursery Stock	all crops	Min 0.5	5	280	NA	NA	215	NA	NA	32000	NA	NA	4.0E-5/ 8.0E-5	1.6E-6/ 3.3E-6	NA
for Application of High Pressure Handwand (2d)			Max 2.5		55	1210	NA	45	NA	940	6400	NA	NA	1.9E-4/ 3.8E-4	8.2E-6/ 1.7E-5	NA
						Applica	ator Exposure	:								
Applying Sprays with Fixed-Wing	Roots and Tuber Vegetable	carrot, sugar beet, potatoes, dry beans, mint	Min 2.0	350	NA	NA	735	NA	NA	570	NA	NA	72940	NA	NA	1.5E-5/ 3.0E-5
Aircraft–Enclosed Cockpit (3)	Legume Vegetable	ary ocans, mint	Max 2.5		NA	NA	585	NA	NA	455	NA	NA	58355	NA	NA	1.9E-5/ 3.8E-5
	Herbs and Spices	hops	Max 2.5	80	NA	NA	2570	NA	NA	2000	NA	NA	255295	NA	NA	4.2E-6/ 8.4e-6

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates	Daily Acres	Sho	ort-Term I MOEs		Interm	ediate-Term MOEs	n Dermal	Inh	nalation M	IOEs	Cancer		
			(lb ai/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
	Citrus fruits	grapefruit, orange	Max 2.5	125	NA	NA	1645	NA	NA	1280	NA	NA	163390	NA	NA	6.6E-6/ 1.3E-5
	Tree Nuts	almond, walnut	Min 2.5		NA	NA	1645	NA	NA	1280	NA	NA	163390	NA	NA	6.6E-6/ 1.3E-6
			Max 4.5		NA	NA	915	NA	NA	710	NA	NA	90770	NA	NA	1.2E-5/ 2.4E-5
	Cereal Grains	pop, sweet),	Min 1.5	350	NA	NA	980	NA	NA	760	NA	NA	97255	NA	NA	1.1E-5/ 2.2E-5
	Non-Grass animal sorghum grain, alfalfa, clover Feed	Max 2.5		NA	NA	590	NA	NA	455	NA	NA	58355	NA	NA	1.9E-5/ 3.8E-5	
	Oil Seed	peanut, jojoba	Min 1.5	350	NA	NA	980	NA	NA	760	NA	NA	97255	NA	NA	1.1E-5/ 2.2E-5
			Max 2.5		NA	NA	590	NA	NA	455	NA	NA	583550	NA	NA	1.9E-5/ 3.8E-5
		cotton	Max 1.6	350	NA	NA	920	NA	NA	715	NA	NA	91175	NA	NA	1.2E-5/ 2.4E-5
				1200	NA	NA	270	NA	NA	210	NA	NA	26595	NA	NA	4.0E-5/ 8.0E-5
	Stone fruit	nectarine	Max 3.0	125	NA	NA	1370	NA	NA	1065	NA	NA	136155	NA	NA	7.9e-6/ 1.6E-5
	Ornamental plants	Christmas tree, conifer seed	Max 2.5	125	NA	NA	1645	NA	NA	1280	NA	NA	163390	NA	NA	6.6E-6/ 1.3E-5
Applying Sprays with a Groundboom	Roots and Vegetable	potatoes, corn (field, pop,	Min 1.5	80	1530	NA	NA	1190	NA	NA	39100	NA	NA	8.2E-6/ 1.6E-5	7.4E-6/ 1.5E-5	2.4E-6/ 4.8E-6
Sprayer (4)		sweet) sorghum grain, alfalfa, clover,														
	Non-grass animal feed	cotton, peanut, jojoba and mint	Max 2.5		920	NA	NA	715	NA	NA	23460	NA	NA	1.6E-5/ 3.2E-5	1.3E-5/ 2.5E-5	4.2E-6/ 8.4E-6
	oil seed															
	herbs and spices															

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates	tes Acres		ort-Term D MOEs	ermal	Interme	ediate-Term MOEs	n Dermal	Inhalation MOEs			Cancer		
			(lb ai/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
Applying Sprays with an Airblast	pome fruits	quince, cherry, prunes, orange,	Min 1.5	40	120	NA	NA	95	140	NA	12860	NA	NA	9.1E-5/ 1.8E-4	6.4E-5/ 1.3E-4	1.2E-5/ 2.4E-5
Sprayer (5)	stone fruits	grapefruit, lemon, lime,							1,02	1.52	223					
	citrus fruits	tangerine, boysenberry, current, hops,														
	berries	raspberry, date, persimmons,														
	tropical & subtropical fruits small fruits tree nuts ornamental plants	almond, filbert, macadamia nut, pecan,		40	120	750	30	90	570	4285	NA	NA	2.8E-4/ 5.6E-4	1.9E-4/ 3.8E-4	4.2E-5/ 8.4E-5	
		pistachio, walnut,	chio, but, stmas Tree tation, fers, shade													
		Christmas Tree plantation,														
		trees														
Applying Liquids with a High	non-bearing nursery stock	all crops	Min 0.5	5	570	NA	NA	445	NA	NA	17580	NA	NA	2.3E-5/ 4.6E-5	1.2E-5/ 2.3E-5	NA
Pressure Handwand (6)			Max 2.5		115	NA	NA	90	250	NA	3515	NA	NA	1.1E-4/ 2.2E-4	5.8E-5/ 1.2E-4	NA
		_				Flagg	er Exposure									
Flagging During Aerial Spray	Roots & tuber Vegetable	carrot, sugar beet, potatoes,	Min 2.0	350	335	NA	NA	260	NA	NA	14170	NA	NA	3.6E-5/ 7.2E-5	NA	NA
Application (7)	legume vegetable	dry beans, mint	Max 2.5		265	NA	NA	210	NA	NA	11335	NA	NA	4.4E-5/ 8.8E-5	NA	NA
	herbs and spices	hops	Ma 2.5	80	1170	NA	NA	910	NA	NA	49600	NA	NA	9.6E-5/ 1.9E-5	NA	NA
	Citrus fruits	grapefruit, orange	Max 2.5	125	750	NA	NA	580	NA	NA	31745	NA	NA	1.7E-5/ 3.3E-5	NA	NA
	Tree Nut	almond, walnut	Min 2.5	125	750	NA	NA	580	NA	NA	31745	NA	NA	1.7E-5/ 3.3E-5	NA	NA
			Max 4.5		415	NA	NA	325	NA	NA	17635	NA	NA	2.9E-5/ 5.8E-5	NA	NA

Exposure Scenario (Scenario #)	Crop Group	Crop	Application Rates (lb ai/acre)	Daily Acres Treated	Sho	Short-Term Dermal Intermediate-Term Derma MOEs MOEs						nalation M	OEs	Cancer		
			(ib al/acre)	Treated	Base line	PPE	Eng Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. Control	Base line	PPE	Eng. control
	cereal grain (field, pop, sweet),	sweet),	Min 1.5	350	445	NA	NA	345	NA	NA	18895	NA	NA	2.8E-5/ 5.6E-5	NA	NA
non-grass feed	non-grass animal feed	sorghum grain, alfalfa, clover	Max 2.5		265	NA	NA	210	NA	NA	11335	NA	NA	4.6E-5/ 9.3E-5	NA	NA
	oil seed	cotton	Max 1.6	350	415	NA	NA	325	NA	NA	17715	NA	NA	2.8E-5/ 5.6E-5	NA	NA
				1200	120	NA	NA	100	NF	NA	5165	NA	NA	1.0E-4/ 2.0E-4	NA	NA
		Peanut, jojoba	Min 1.5	350	445	NA	NA	345	NA	NA	18895	NA	NA	2.8E-3/ 5.6E-3	NA	NA
			Max 2.5		265	NA	NA	210	NA	NA	11335	NA	NA	4.6E-5/ 9.3E-5	NA	NA
	Stone fruits	nectarine	Max 3.0	125	625	NA	NA	485	NA	NA	26455	NA	NA	1.9E-5/ 3.8E-5	NA	NA
	Ornamental plants	Christmas tree conifer seed	Max 2.5	125	750	NA	NA	580	NA	NA	31745	NA	NA	1.7E-5/ 3.4E-5	NA	NA

Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor.

4.3.2 Occupational Postapplication Exposure Scenarios

EPA has determined that there are potential short and intermediate-term postapplication exposures to individuals entering treated fields for the purpose of postapplication activities.

b Short-term Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (60 kg).

c Intermediate-term Daily Dermal Dose (mg/kg/day) = Daily Dermal Exposure (mg/day)/ Body weight (70 kg).

d Short-term Dermal MOE = NOAEL (6 mg/kg/day)/Short-term Daily Dermal Dose (mg/kg/day).

e Intermediate-term MOE = NOAEL (4 mg/kg/day)/Intermediate-term Daily Dermal Dose (mg/kg/day)

Baseline inhalation unit exposure represents no respirator

Daily Inhalation Dose (mg/kg/day) = Daily Inhalation Exposure (mg/day)/ Body weight (70 kg).

h Short-Intermediate-term Inhalation MOE = LOAEL (49.6 mg/kg/day)/ Daily Inhalation Dose (mg/kg/day).

For the purpose of conducting this assessment, indicator crop groups/activities, and assumptions regarding application rates and dermal transfer coefficients for these crop groups were selected that are likely to be representative of postapplication exposures to propargite. The crop groups/activities listed below were chosen because appropriate residue data were available, and exposure assumptions could be made that would be inclusive of other similar crop types/activities. Although several studies have been submitted, it was still necessary to use standard transfer coefficients and crop-specific residues as substitutes to represent other crops. Also, the development of these exposure scenarios followed the guidance provided in the Science Advisory Council for Exposure Policy Memo Number 003. The postapplication exposure scenarios include the following:

- All activities (weeding and irrigation, harvesting) associated with **legume vegetable**, **roots and tuber vegetable** and **non grass animal feed** groups. This scenario is assumed to be representative of exposures from typical weeding and irrigation activities. DFR and passive dosimetry data for dry beans were used, based on studies using an application rate of 2.46 lb ai/acre. This application rate is consistent with the application rates for most crops in these groups. A dermal transfer coefficient of 60 cm²/hr was calculated from a weeder reentry study (MRID No. 426891-04) to represent weeding and hoeing activities associated with these groups. For irrigation a generic dermal transfer coefficient of 1,000 cm²/hr was used. Harvesting is highly mechanized.
- All activities (harvesting, weed control, irrigation, fertilization, pruning, and frost protection) associated with **citrus** fruits. This scenario is assumed to be representative of exposures from all activities. DFR data for navel oranges were used, based on a study using maximum application rates of 3.15 lb ai/acre and 4.5 lb ai/acre. A generic dermal transfer coefficient of 10,000 cm²/hr was used to represent all activities associated with citrus fruits.
- All activities (pruning, brush removal, weed control, mowing, tree spraying, tree removal and replanting, irrigation, and harvesting) associated with **stone fruits, pome fruits, tropical and subtropical fruits, and ornamental plants.** This scenario is assumed to be representative of exposures from all activities. DFR data for apple were used, based on a study using application rates of 3.6 lb ai/acre and 1.7 lb ai/acre in states of Vermont and Washington. A range of generic dermal transfer coefficients of 2,500 cm²/hr, 4,000 cm²/hr and 10,000 cm²/hr were uses to represent all activities associated within these groups.
- All activities (pruning, fertilization, pest control, weed control, irrigation, and harvesting) associated with **berries**. This scenario is assumed to be representative of exposures from all activities. DFR data for grape were used, based on a study using a maximum application rate of 2.7 lb ai/acre. Generic dermal transfer coefficients of 4,000 cm²/hr was used.
- All activities (pruning, fertilization, pest control, leaf removal, weed control, irrigation, cane throwing, girdling and harvesting)

associated with **small fruits**. This scenario is assumed to be representative of exposures from all activities. DFR and passive dosimetry data for grapes were used, based on studies using a maximum application rate of 2.7 lb ai/acre. Dermal transfer coefficient of 878 cm²/hr for tractor driver, 10,246 cm²/hr (cane turner 14 days), 3,713 cm²/hr (cane turner 21 days) and 1,895 cm²/hr (cane turner 28 days) were calculated from a worker reentry study (MRID No.409753-04) to represent cane throwing activities associated with grapes. No chemical specific study was available for raisin grapes, therefore, data from two studies (MRID Nos. 40985601 and 43223901) were used to establish REI. A transfer coefficient of 5,000 was used for raisin grape.

- All activities (pruning, brush removal, weed control, mowing, tree spraying, irrigation, and harvesting) associated with tree nuts. This scenario is assumed to be representative of exposures from all activities. Dermal transfer coefficient of 48.0 cm²/hr was calculated from a worker reentry study (MRID NO. 418486-04) which represents tree shaker scenario. DFR data for almonds were used, based on a study using a maximum application rate of 3.0 lb ai/acre. A generic dermal transfer coefficient of 10,000 cm²/hr was used to represent all other activities associated with tree nuts.
- All activities (weeding and irrigation) associated with **cereal grains**. This scenario is assumed to be representative of exposures from typical weeding and irrigation activities. DFR data for corn were used, based on a study using an application rate of 2.46 lb ai/acre. This application rate is consistent with the application rates for most crops in this group. A generic dermal transfer coefficient of 10,000 cm²/hr was used.
- All activities (weeding and irrigation and harvesting) associated with herbs and spices. This scenario is assumed to be representative of exposures from typical weeding and irrigation activities. DFR data for hops were used, based on a study using an application rate of 1.35 lb ai/acre. A generic dermal transfer coefficient of 4,000 cm²/hr for early season and 10,000 cm²/hr for late season were used for hops. Since no DFR data was submitted for mint, data from a dry bean study (MRID No. 42011801) were used. A generic dermal transfer coefficient of 1,000 was used for mint. Currently, HED conducts post-application exposure and risk assessments assuming that the workers were wearing "typical" work clothing long-sleeved shirt, long pants, shoes, and socks. Additional personal protective equipment is not considered in these assessments.
- All activities (weeding and irrigation, harvesting and pest management) associated with **oil seed crop** group. This scenario is assumed to be representative of exposures from typical weeding and irrigation activities. DFR data for cotton were used, based on studies using an application rate of 1.64 lb ai/acre. This application rate is consistent with the application rates for most crops in these groups. A dermal transfer coefficient of 63 cm²/hr was calculated from a weeder reentry study (MRID No.426891-03) to represent weeding activities associated with oil seed crop group. For early season scouting and late season scouting a generic dermal transfer coefficient of 1,000 cm²/hr and 4,000 cm²/hr were used respectively.

4.3.2.1 Occupational Postapplication Exposure Data Sources and Assumptions

For the purposes of this assessment, regression analysis were conducted using the natural log-transformed DFR data from the above studies to estimate residue levels on various crops on various days for postapplication using the following equation:

```
y = mx + b
```

where:

x = days postapplication;

m = slope of the regression line;

b = constant; and

y = residue on day x.

The summary of regression analysis on submitted studies is presented in Table 11.

Table 11. Summary of Data used for Post Application of Propargite

Crop grouping	DFR Study	Formulatio Type	n	Study Application Rate (lb ai/acre)	\mathbb{R}^2	Initial DFR as a % of Appl. Rate (Day 0 measured values)	Transfer Coefficient	Dissipation (% per day)	½ Life (days)
Legume vegetable, roots and tuber vegetable and non- grass animal feed	Dry beans (MRID 420118-01, 426891-04	Comite EC		2.46	0.96	18.9	60	11	5.97
Citrus	Navel	Omite CR		3.15	0.78	9.2	NA	6	12.1
	oranges MRID	Omite 30W	I	3.15	0.65	4.9	NA	4	15.5
	409090-03	Omite CR		4.5	0.74	10.4	NA	5	12.9
Stone fruits, Pome fruits, Tropical and subtropical fruits,	Apple MRID 409090-04	Omite CR	V T	3.6	0.98	4.2	NA	10	6.8
ornamental plants	409090-04	CK	W A	3.6	0.21	4.5	NA	4	18.1
		Omite 30W	V T	3.6	0.99	4.2	NA	10	6.5
			W A	3.6	0.37	2.1	NA	3	20.6
Small fruits	Grape	Omite 30W	I	2.7	0.72	2.7	878	6	10.7
	MRID 409753-01						1895		
	MRID 409753-04						3713		
							10246		
Tree nuts	Almond MRID 418486-04 MRID 418486-03	Omite 6E		3.0	0.79	6.0	48	5	13.6
Cereal grain	Corn MRID 416803-02	Comite EC	!	2.46	0.72	6.4	NA	18	3.5
Herbs and spices	Hops MRID 426891-03	Comite EC		1.35	0.72	14.5	NA	4	18.6
Oil seed	Cotton MRID 426891-03 MRID 414578-06	Comite EC		1.64	0.92	11	63	11	6.2

The postapplication exposure assessment encompasses all of the major uses of propargite throughout the country. It is difficult to assess all of the "typical" agricultural uses for propargite (i.e., actual or predominate application rates and climatological conditions), and therefore, an assessment has been developed which is believed to be realistic and yet provides a reasonable certainty that the exposures are not underestimated. The assumptions and uncertainties are identified below to be used in risk

management decisions:

- Crop Specific Residues: A multitude of crops are treated with propargite and crop specific residue data are not available for all situations. Therefore, the use of the available data to "simulate" residues on other crops introduces uncertainties in the setting of reentry intervals. It is reasonable to believe that the residues monitored in the available studies approximate the residues on other crops, but the extent that these residues might be an under- or overestimate is unknown. The DFR results from these crops may alter the surrogate assessment for determining REIs.
- *Transfer Coefficients:* The transfer coefficients selected are based on the activities monitored in the submitted studies and on HED's policy for surrogate values until the results of the Agricultural Reentry Task Force (ARTF) are available. These values are believed to be reasonable estimates that would not underestimate the risks.
- Exposure Duration: The amount of time (e.g., days) that a worker would be involved in postapplication activities is not available. Therefore, both short-term and intermediate-term exposure durations are provided and the intermediate-term duration is believed to be most representative for the postapplication exposures. Furthermore, the REIs are calculated at the residue level predicted on a specific day after treatment; subsequent declining residue levels (i.e., average residues under the dissipation curve) are not incorporated into the assessment because of the lack of exposure duration data (including the fact that harvesters may travel to multiple fields). Note: Scouts are assumed to be exposed eight hours per day, which may be an overestimation.

4.3.2.2 Occupational Postapplication Risk Characterization

Short-term Risks

The target dermal MOE is 100 for propargite. The results of the occupational postapplication assessment are presented in Tables 13-27, and are summarized below:

- Propargite MOEs equal or exceed 100 for weeding and hoeing associated with legume vegetable, roots and tuber vegetable and non grass animal feed on the 1st day. For irrigation, propargite MOEs equal or exceed 100 on the 3rd day (2.5 lb ai/acre).
- Propargite MOEs equal or exceed 100 for all activities associated with citrus at 2.5 lb ai acre on the 31st day, 3.15 lb ai/acre on the 35th day, and at 4.5 lb ai/acre at the 41st day.
- Propargite MOEs equal or exceed 100 for sort/pack /tree removal of ornamental associated with stone fruits, pome fruits, tropical and subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on 0,0, 1st and 6th day, respectively. Propargite MOEs equal or exceed 100 for mowing/irrigation/weed control associated with stone fruits, pome fruits, tropical and

subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on 0,0, 5th and 11th day respectively. Propargite MOEs equal or exceed 100 for harvesting associated with stone fruits, pome fruits, tropical and subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on 0, 9th, 14th and 20th day. respectively.

- Propargite MOEs equal or exceed 100 for all activities associated with berries on the 2nd day (2.0 lb ai/acre)
- Propargite MOEs equal or exceed 100 for associated with harvesting grapes at 2.88 lb ai/acre on the 21th day (raisin grape 11th day).
- Propargite MOEs equal or exceed 100 for tree shakers associated with tree nuts at 3.0 lb and 4.5 ai/acre on first day and for all other activities on the 26th, 34th day respectively.
- Propargite MOEs equal or exceed 100 for all activities with cereal grains, non-grass animal feed at 2.46 lb ai/acre on the 9th day.
- Propargite MOEs equal or exceed 100 for weeding and irrigation for hops at 2.5 lb ai/acre on the 45th day and for harvesting on the 67th day.
- Propargite MOEs equal or exceed 100 for all activities on mint at 2.5 lb ai/acre on the 3rd day.
- Propargite MOEs equal or exceed 100 for weeding and hoeing for oil seed at 1.6 lb ai/acre on 0 day, for early season scouting on 0 day and for late season scouting on the 8th day.

Intermediate-term Risks

The target MOE is 100 for propargite. The resulting occupational postapplication assessments, as shown in Tables 13 through 27, indicate that:

- Propargite MOEs equal or exceed 100 for weeding and hoeing associated with legume vegetable, roots and tuber vegetable and non grass animal feed on the 1st day. For irrigation on the 5th day (2.5 lb ai/acre).
- Propargite MOEs equal or exceed 100 for all activities associated with citrus at 2.5 lb ai /acre on the 35th day, 3.15 lb ai/acre on the 39th day, and at 4.5 lb ai/acre at the 45th day.
- Propargite MOEs equal or exceed 100 for sort/pack /tree removal of ornamental associated with stone fruits, pome fruits, tropical and subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on first, 3rd and 9th day. respectively. Propargite MOEs equal or exceed 100 for mowing/irrigation/weed control associated with stone fruits, pome fruits, tropical and subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on 0,3rd, 8th and 13th day respectively. Propargite MOEs equal or exceed 100 for harvesting associated with stone

fruits, pome fruits, tropical and subtropical fruits, and ornamental plants at 0.5, 1.5, 2.5 and 4.5 lb ai/acre on the 1st, 12th, 16th and 20th day. respectively.

- Propargite MOEs equal or exceed 100 for all activities associated with berries on the 6th day (2.0 lb ai/acre).
- Propargite MOEs equal or exceed 100 for harvesting grapes at 2.88 lb ai/acre on the 27th day.
- Propargite MOEs equal or exceed 100 for tree shakers associated with tree nuts at 3.0 and 4.5 lb ai/acre on the first day and for all other activities on the 31st and 39th day respectively.
- Propargite MOEs equal or exceed 100 for all activities with cereal grains, non-grass animal feed at 2.46 ai/acre on the 10th day.
- Propargite MOEs equal or exceed 100 for weeding and irrigation for hops at 2.5 lb ai/acre on the 51st day and for harvesting on the 73rd day.
- Propargite MOEs equal or exceed 100 for all activities on mint at 2.5 lb ai/acre on the 5th day.
- Propargite MOEs equal or exceed 100 for weeding and hoeing for oil seed at 1.6 lb ai/acre on 0 day, for early season scouting on 0 day and for late season scouting on the 10th day.

Table 12. Summary of the Short- and Intermediate-Term Reentr	y Intervals (REIs) for the Contact Rates and Cro	p Grouping Matrix.

· ·		CI (T DEI(I)	T (1' (T DET (1)
Crop grouping	Crop	Short Term- REI (days)	Intermediate -Term REI (days)

			2.5 lb	ai/A			2.5 it	ai/A	
Roots and Tuber Vegetable	Carrot, Potato, Sugar beet, Bean dry, Alfalfa, Clover		:	3			:	5	
Legume Vegetables									
Non-grass Animal Feed									
Citrus Fruits	Crop	2.5 lb ai/A	3.15 lb ai/A	4. II ai		2.5 lb ai/A	3.15 lb ai/A		5 b /A
	Orange, Lemon, Lime, Tangerine, Grapefruit,	31	35	4	1	35	39	4	5
Pome Fruits	Crop	0.5 lb ai/A	1.5 lb ai/A	2.5 lb ai/A	4.5 lb ai/A	0.5 lb ai/A	1.5lb ai/A	2.5 lb ai/A	4.5 lb ai/A
Stone Fruits	Quince, Cherry, Nectarine, Prune, Avocado, Date, Persimmons, X mas Tree, Ornamental	0	9	14	20	1	12	16	22
Tropical and Subtropical Fruits	and/or shade trees Ornamental, Herbaceous Plants								
Ornamental Plants									
Berries	Crop		2.0 11	o ai/A			2.0 lb	ai/A	
	Boysenberry, Currant, Raspberry		<u>′</u>	2			(5	
Small fruits	Crop		3.016	ai/A			3.0 lb	ai/acre	
	Grape (raisin)		1	1			1	5	
	Grape (others)		2	1			2	7	
Tree Nuts	Crop	3.0 lb	ai/acre	4.5 lt	ai/A	3.0 lb	ai/A	4.5 lt	ai/A
	Almond, Filbert, Macadamia, Pecan, Pistachio, Walnut	2	.6	3	4	3	1	3	9
	Almond, Filbert, Macadamia, Pecan, Pistachio, Walnut (tree shaking)	(0	()	()	()
	Crop		2.5 11	o ai/A			2.5 11	ai/A	
Cereal grains	Corn (unspecified, field, pop, sweet) Sorghum, grain		9	9			1	0	
Herbs and Spices	Crop		2.5 11	o ai/A			2.5 11	ai/A	
	hops		6	i7			7	3	
	mint			3				5	
Oil seed	Crop		1.6 lt	o ai/A			1.6 lt	ai/A	
	Cotton, Peanut, Jojoba			8			1	0	

Cancer Risks

REIs have been estimated using the short- and intermediate-term endpoints. Additionally, the cancer endpoint was used to estimate REIs. HED's target range for cancer probabilities are 1E-4 to 1E-6

for occupational assessments. Historically, setting REIs on cancer endpoints has been difficult because of the need for lifetime use assumptions. To estimate the LADD the typical application rate, the number of days worked per year, and the number of years one would be exposed during a working lifetime are needed. Each one of these variables are dependent upon many factors. For example, the number of days worked per year must correspond to the days worked when the pesticide of concern has been applied. Additionally, the residue dissipation over the work interval should be estimated. Without an estimate for residue dissipation one needs to assume (unrealistically) that the worker travels from one treated field to another so that the highest residue value is always found. In the case of propargite, a screening estimate was developed because lifetime use data are not available. The screening level estimate assumed: (1) that workers would be exposed for 7 to 14 days (for short- and intermediate-term durations, respectively); (2) no residue dissipation; (3) range of application rates; and (4) a worker would be exposed for 35 years. Based on these assumptions, the cancer probabilities on the day the REIs were estimated using the subchronic endpoints, ranged from 2.9E-4 to 3.2E-4. Although, the cancer estimates are greater than the criteria for 1E-4, further refinements are not made at this time because of the lack of use data and/or more appropriate methods for setting REIs based on cancer endpoints. HED does not believe that the cancer estimates are of concern given the high end assumptions used in the calculations.

Table 13. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Dry Beans

			appl	oeing activitie ied at 2.5 lb a Coefficient = 0						applied at 2	ities Dry Bean .5 lb ai/acre ent =1000 cm ²		
D A	DFR ^d (μg/cm ²)		l Dose ^e g/day)	Short- term	Intermediate- term MOE ^g	LADD ^h	Canceri	Derma (mg/k		Short- term	Intermedi ate-term	LADD ^h	Cano
T ^c		BW 60	BW 70	MOE ¹	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$								
0	4.55	0.0051	0.0044	1200	915	1.79E-4	3.60E-5	0.0849	0.0728	70	55	2.99E3	6.011
3	3.21	NA	NA	NA	NA	NA	NA	0.0600	0.0513	100	80	2.11E-3	4.24]
5	2.54	NA	NA	NA	NA	NA	NA	NA	0.0406	NA	100	1.6E-3	3.221

^aAssumed to represent weeding and hoeing

Table 14. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Citrus All activities - Citrus All activities - Citrus applied at 2.5 lb ai/acre applied at 4.5 lb ai/acre Transfer Coefficient = 10,000 cm²/hr^a Transfer Coefficient = 10,000 cm²/hr^a T DFR^c $Cancer^h$ D Dermal Dose^d Short-Inte- $LADD^g$ DFR^c Dermal Dose^d Short-Int- $LADD^g$ Cancer^h DFR^c Derma A (mg/kg/day) term term (mg/kg/day) term term (mg/k $T^{\scriptscriptstyle b}$ MOE^e MOE^f MOE^e MOE^f BWBWBWBWBW60 70 60 70 60 0 3.985 0.744 0.64 5 2.6E-2 5.3E-3 2.214 0.41 0.35 15 10 1.46E-2 2.9E-3 2.789 0.52 8 0.203 25 7.14E-3 1.4E-3 0.604 3.97E-3 8.0E-4 21 1.087 0.17 30 0.11 0.10 55 40 0.761 0.14 28 0.705 0.132 0.11 45 35 4.63E-3 9.3E-4 0.391 0.07 0.06 80 65 2.57E-3 5.2E-4 0.493 0.09 31 0.585 0.109 0.09 55 45 3.85E-3 7.7E-4 0.325 0.06 0.05 100 75 2.14E-3 4.3E-4 0.410 0.08 35 0.457 0.09 0.07 70 3.0E-3 6.0E-4 0.254 0.04 1.67E-3 3.4E-4 0.320 0.06 55 NA NA 100

^bAssumed to represent Irrigation

^cDAT = days after treatment.

^dBased on DFR data from a study of postapplication Propargite residues on dry-beans using an application rate of 2.46 lb ai/acre (MRID #426891-04)

^eDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^fShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

 $^{^{}g}$ Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

^hFor agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. where adult body weight = 70 kg,.

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

		Tra	appli	activities - 0 ed at 4.5 lb efficient = 1	ai/acre	hr ^a				apı	Il activities plied at 2.5 Coefficient =	lb ai/acre	m²/hrª			Т	applie	activities - C d at 3.15 lb efficient = 1	ai/acre	/hrª	
D A	DFR ^c	Dermal (mg/kg		Short- term	Inte- term	LADD ^g	Cancer ^h	DFR ^c	Derma (mg/k	l Dose ^d g/day)	Short- term	Int- term	LADD ^g	Cancer ^h	DFR°	Derma (mg/k		Short- term	Int- term	LADD ^g	Cancer ^h
T ^b		BW 60	BW 70	MOE ^e	MOE ^f				BW 60	BW 70	MOE	MOE ^f				BW 60	BW 70	MOE ^e	MOE ^f		
39	0.357	0.1	0.04	90	70	2.35E-3	4.7E-4	NA	NA	NA	NA	NA	NA	NA	0.250	NA	0.04	NA	100	1.63E-3	3.3E-4
41	0.315	0.06	0.05	100	80	2.07E-3	4.2E-4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
45	0.246	NA	0.04	NA	100	1.62E-3	3.3E-4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

^aAssumed to represent all activities applying Omite CR at 3.15 lb ai/acre

Table 15. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Apple

^bDAT = days after treatment.

^{&#}x27;Based on DFR data from a study of postapplication of Propargite (Omite CR®) on navel oranges using an application rate of 3.15 lb ai/acre (MRID # 409090-30). Data normalized to an application rate of 2.5 lb ai/acre. (labeled application rate for the rest of crops within citrus group)

^dDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^eShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

 $^{^{\}rm f}$ Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

^gFor agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult body weight = 70 kg,.

 $^{^{}h}$ Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01×10^{-1} (mg/kg/day) $^{-1}$

		a	pplication	rate 0.5 lb					ap	plication i	ation/weed o ate 0.5 lb a cient 4,000	i/acre				Harv oplication ra sfer coeffici			
D A	$(\mu g/cm^2)$ (mg/kg/day) term term								l Dose ^e (g/day)	Short- term	Inter- term	LADD°	Canceri	Derma (mg/k	l Dose ^e g/day)	Short- term	Inter- term	LADD°	Canceri
\mathbf{T}^{d}		BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE	MOE ^g			BW 60	BW 70	MOE ^f	MOE ^g		
0	0.3	0.0128	0.011	470	365	4.51E-4	9.07E-5	0.0205	0.0176	290	230	7.22E-4	1.45E-4	0.0513	0.0439	117	90	1.81E-3	3.64E-4
1	0.25	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0395	NA	100	1.63E-3	2.8E-4

^aAssumed to represent sort/pack/tree removal

0.5 lb

Table 16. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Apple, continued

^bAssumed to represent mowing/irrigation/weed control

^cAssumed to represent harvesting

^dDAT = days after treatment

^eBased on DFR data from a study of postapplication of Propargite (Omite 30 w [®]) on apple using an application rate of 3.6 ai/acre (MRID # 409090-04). Data normalized to present application of Propargite at

^fDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^gShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

^hIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult body weight = 70 kg..

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

			t/pack/tree i application ransfer coef	rate 1.5 lb	ai/acre				aj	plication ra	tion/weed coate 1.5 lb ai/cient 4,000 c	acre			a _j Tran	Hary oplication ra sfer coeffic	vesting ate 1.5 lb a ent 10,000	i/acre) cm²/hr°	
D A	DFR ^e (μg/cm ²)	Dermal (mg/kg		Short- term	Inter- term	LADD ⁱ	Canceri	Dermal (mg/kg		Short- term	Inter- term	LADD°	Canceri		l Dose ^e (g/day)	Short- term	Inter- term	LADD°	Canceri
T^{a}		BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE ^f	MOE ^g			BW 60	BW 70	MOE ^f	MOE		
0	0.8	0.0384	0.0330	150	120	1.35E-3	2.71E-4	0.0615	0.0527	100	75	2.17E-3	4.36e-4	0.1538	0.1318	40	30	5.42E-3	1.09E-3
3	0.60	NA	NA	NA	NA	NA	NA	NA	0.0384	NA	105	1.58E-4	3.18E-5	0.1121	0.0961	55	40	3.95E-3	7.94E-4
7	0.39	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0736	0.0630	80	65	2.59E-3	5.21E-4
9	0.32	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0596	0.0511	100	80	2.10E-3	4.22E-4
12	0.23	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0372	NA	105	1.53E-3	3.08E-4

^aAssumed to represent sort/pack/tree removal

Table 17. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Apple, continued

^bAssumed to represent mowing/irrigation/weed control

^cAssumed to represent harvesting

^dDAT = days after treatment

Based on DFR data from a study of postapplication of Propargite (Omite 30 w ®) on apple using an application rate of 3.6 ai/acre (MRID # 409090-04). Data normalized to represent an application rate of 1.5 lb ai/acre.

^fDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^gShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

hIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult body weight = 70 kg..

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

			ort/pack/tree application ransfer coe	rate 2.5 lb	ai/acre					application	ation/weed rate 2.5 lb a icient 4,000	i/acre				plication i	rvesting rate 2.5 lb a cient 10,000		
D A	DFR ^e (μg/cm ²)	Derma (mg/k		Short- term	Inter- term	LADDi	Canceri		l Dose ^e g/day)	Short- term	Inter- term	LADD°	Canceri	Dermal (mg/k		Short- term	Inter- term	LADD°	Canceri
\mathbf{T}^{d}		BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE ^f	MOE ^g			BW 60	BW 70	MOE ^f	MOE ^g		
0	1.4	0.0641	0.0549	95	75	2.26E-3	4.54E-4	0.1025	0.0879	60	45	3.61E-3	7.26E-4	0.2563	0.2197	25	20	9.03E-3	1.82E-3
1	1.24	0.0577	0.0494	105	80	2.03E-3	4.08E-4	0.0923	0.0791	65	50	3.25E-3	6.53E-4	0.2307	0.1977	25	20	8.13E-3	1.63E-3
3	1.00	NA	0.0400	NA	100	1.65E-3	3.32E-4	0.0747	0.0641	80	60	2.63E-3	5.29E-4	0.1868	0.1602	30	25	6.58E-3	1.32E-3
5	0.81	NA	NA	NA	NA	NA	NA	0.0605	0.0519	100	75	2.13E-3	4.28E-4	0.1513	0.1297	40	30	5.33E-3	1.07E-3
8	0.59	NA	NA	NA	NA	NA	NA	NA	0.0378	NA	105	1.55E-3	3.12E-4	0.1103	0.0946	55	40	3.89E-3	7.82E-4
14	0.31	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0586	0.0503	102	75	2.07E-3	4.16E-4
16	0.25	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0407	NA	100	1.67E-3	3.36E-4

^aAssumed to represent sort/pack/tree removal

Table 18. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Apple, continued

^bAssumed to represent mowing/irrigation/weed control

^cAssumed to represent harvesting

^dDAT = days after treatment

Based on DFR data from a study of postapplication of Propargite (Omite 30 w e) on apple using an application rate of 3.6 ai/acre (MRID # 409090-04). Data normalized to represent an application rate of 2.5 lb ai/acre.

^fDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^gShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

hIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult body weight = 70 kg,.

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

		a	/pack/tree re pplication r nsfer coeffi	ate 4.5 lb at	i/acre				a	owing/irriga pplication r insfer coeffi	ate 4.5 lb ai	/acre				application	arvesting rate 4.5 lb icient 10,00		
D A	DFR ^e (μg/cm ²)	Derma (mg/k		Short- term	Inter- term	LADD ⁱ	Canceri	Derma (mg/k		Short- term	Inter- term	LADD°	Canceri		l Dose ^e (g/day)	Short- term	Inter- term	LADD°	Cancer ⁱ
Tu		BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE ^f	MOE ^g			BW 60	BW 70	MOE ^f	MOE ^g		
0	2.5	0.1153	0.0989	50	40	4.06E-3	8.16E-4	0.1845	0.1582	35	25	6.50E-3	1.31E-3	0.4613	0.3954	15	10	1.63E-2	3.28E-3
3	1.80	0.0841	0.0721	70	55	2.96E-3	5.95E-4	0.1345	0.1153	45	35	4.47E-3	8.98E-4	0.3363	0.2883	20	15	1.18E-2	2.37E-3
6	1.31	0.0600	0.05	100	75	2.16E-3	4.34E-4	0.0981	0.0841	60	50	3.45E-3	6.93E-4	0.2452	0.2102	25	20	8.64E-3	1.74E-3
9	0.96	NA	0.04	NA	105	1.57E-3	3.16E-4	0.0715	0.0613	85	65	2.52E-3	5.07E-4	0.1787	0.1532	35	25	6.30E-3	1.27E-3
11	0.78	NA	NA	NA	NA	NA	NA	0.0579	0.0496	100	80	2.04E-3	4.10E-4	0.1448	0.1241	40	30	5.10E-3	1.03E-3
13	0.63	NA	NA	NA	NA	NA	NA	NA	0.0402	NA	100	1.65E-3	3.32E-4	0.1173	0.1005	50	40	4.13E-3	8.30E-4
20	0.30	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0561	0.0481	106	85	1.98E-3	3.98E-4
22	0.24	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0389	NA	105	1.60E-3	3.22E-4

^aAssumed to represent sort/pack/tree removal

Table 19. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Boysenberry, Current and Raspberry (Black, Red)

^bAssumed to represent mowing/irrigation/weed control

^cAssumed to represent harvesting

^dDAT = days after treatment

Based on DFR data from a study of postapplication of Propargite (Omite 30 w) on apple using an application rate of 3.6 ai/acre (MRID # 409090-04). Data normalized to 4.5 lb ai/acre for Avocado.

^fDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^gShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

^hIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

¹For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult body weight = 70 kg..

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01×10^{-1} (mg/kg/day)

			appl	activities - Berries ied at 2.0 lb ai/acre pefficient = 4,000 cm²/l	hr ^a										
D A	$egin{array}{ccccc} A & & (\mu g/cm^2) & & (mg/kg/day) & & & & & & & & & & & & & & & & & & &$														
T ^o	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$														
0	0.9	0.0670	0.0574	90	70	2.36E-3	4.74E-4								
1	0.84	0.0629	0.0539	95	75	2.22E-3	4.46E-4								
2	0.79	0.0592	0.0507	100	80	2.08E-3	4.18E-4								
6	0.62	NA	0.0396	NA	100	1.63E-3	3.28E-4								

^aAssumed to represent all activities

Table 20. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Grape

^bDAT = days after treatment.

Based on DFR data from a study of postapplication of Propargite (Omite 6E®) on grape using an application rate of 2.88 ai/acre (MRID # 418486-03). Data normalized to account for an application rate of 2.0 lb ai/acre. ^dDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^eShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

Fintermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. where adult body weight = 70 kg,.

^hEstimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

			Tractor application ransfer coef		ai/acre					pplication ra	rners 14 day ate 2.88 lb a cient 10246	ni/acre				pplication r	rners 21 da ate 2.88 lb a icient 3713	ai/acre	
D A	DFR ^e (μg/cm ²)		l Dose ^f g/day)	Short- term	Inter- term	LADD ⁱ	Canceri	Derma (mg/k	l Dose ^e	Short- term	Inter- term	LADD°	Canceri		l Dose ^e .g/day)	Short- term	Inter- term	LADD°	Cancer ⁱ
\mathbf{T}^{d}	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE ^f	MOE ^g			BW 60	BW 70	MOEf	MOE ^g		
0	1.3	0.0457	0.0181	285	220	7.45E-4	4.92E-5	0.2470	0.2117	25	20	8.70E-3	1.75E-3	0.0895	0.0767	65	50	3.15E-3	6.33E-4
3	1.07	NA	NA	NA	NA	NA	NA	0.2051	0.1758	30	25	7.23E-3	1.45E-3	0.0743	0.637	80	65	2.62E-3	5.27E-4
7	0.84	NA	NA	NA	NA	NA	NA	0.1601	0.1373	35	30	5.64E-3	1.13E-3	0.1601	0.1373	105	80	2.04E-3	4.10E-4
11	0.65	NA	NA	NA	NA	NA	NA	NA	NA	50	40	4.37E-3	8.78E-4	NA	0.1072	NA	105	1.60E-3	3.22E-4
14	0.54	NA	NA	NA	NA	NA	NA	0.1039	0.0890	90	45	3.66E-3	7.36E-4	NA	NA	NA	NA	NA	NA
21	0.35	NA	NA	NA	NA	NA	NA	0.0673	0.0577	100	70	2.37E-3	4.76E-4	NA	NA	NA	NA	NA	NA
23	0.31	NA	NA	NA	NA	NA	NA	NA	0.0510	NA	80	2.10E-3	4.22E-4	NA	NA	NA	NA	NA	NA
27	0.24	NA	NA	NA	NA	NA	NA	NA	0.0398	NA	100	1.64E-3	3.30E-4	NA	NA	NA	NA	NA	NA

^aAssumed to represent tractor driver entering after two days

body

Table 21. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Grape, continued

^bAssumed to represent cane turners entering after 14 days

^cAssumed to represent cane turners entering after 21 days

^dDAT = days after treatment

^eBased on DFR data from a study of postapplication of Propargite (Omite 6 E [®]) on grape using an application rate of 2.88 ai/acre (MRID # 418486-03)

^fDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^gShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

^hIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult weight = 70 kg..

Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

			applie	e turners 28 days d at 2.88 lb ai/ac efficient = 1895	re						Harvesting oplied at 2.88 lb ai/acr Coefficient =15000		
D A	DFR ^d (μg/cm ²)		al Dose ^e kg/day)	Short-term MOE ^f	Intermediate- term MOE ^g	LADD ^h	Canceri	Dermal (mg/k		Short- term	Intermediate- term MOE ^g	LADD ^h	Canceri
T ^c		BW 60	BW 70					BW 60	BW 70	MOE ^f			
0	1.3	0.0457	0.0391	130	100	1.61E-3	3.24E-4	0.3615	0.3099	15	15	1.27E-2	2.55E-3
3	1.07	NA	NA	NA	NA	NA	NA	0.3003	0.2574	20	15	1.06E-2	2.13E-3
7	0.84	NA	NA	NA	NA	NA	NA	0.2345	0.2010	25	20	8.26E-3	1.66E-3
14	0.54	NA	NA	NA	NA	NA	NA	0.1520	0.1303	40	30	5.36E-3	1.08E-3
21	0.35	NA	NA	NA	NA	NA	NA	0.0986	0.0845	60	50	3.47E-3	6.97E-4
29	0.21	NA	NA	NA	NA	NA	NA	0.0601	0.0515	100	80	2.12E-3	4.26E-4
33	0.17	NA	NA	NA	NA	NA	NA	NA	0.0402	NA	100	1.65E-3	3.32E-4

^aAssumed to represent cane turners entering after 28 days

adult

Table 22. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for tree nuts

^bAssumed to represent harvesting

^cDAT = days after treatment.

dBased on DFR data from a study of postapplication Propargite residues (Omite 6 E ®) on grape using an application rate of 2.88 ai/acre (MRID # 418486-03)

based on Dr Radat on a study of postagraphication 1 ropagite restates (office C = C) of graph using an ePose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

Short-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

^hFor agricultural scenarios, LADD = [DFR (µg/cm²) x Tc (cm²/hr) x mg/1,000 µg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]., where body weight = 70 kg.

Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = $2.01x10^{-1}$ (mg/kg/day)⁻¹

			Open cab tr applied at 3.		hr ^a			All other activities applied at 3.0lb ai/acre Transfer Coefficient =4,000 cm ² /hr ^b					
D A				Short- Intermediate- term term MOE ^g		LADD ^h	Canceri	Dermal Dose ^e (mg/kg/day)		Short-term MOE ^f	Intermediate-term MOE ^g	LADD ^h	Cancer ⁱ
\mathbf{T}^{c}		BW 60	BW 70	MOE ^f				BW 60	BW 70				
0	3.1	0.0027	0.0023	2250	1750	9.46E-5	1.09E-5	0.2285	0.1958	25	20	8.05E-3	1.62E-3
7	2.14	NA	NA	NA	NA	NA	NA	0.1596	0.1368	40	30	5.62E-3	1.13E-3
14	1.49	NA	NA	NA	NA	NA	NA	0.1114	0.0955	55	40	3.92E-3	7.88E-4
21	1.04	NA	NA	NA	NA	NA	NA	0.0778	0.0667	75	60	2.74E-3	5.51E-4
26	0.81	NA	NA	NA	NA	NA	NA	0.0602	0.0516	100	80	2.12E-3	4.26E-4
28	0.73	NA	NA	NA	NA	NA	NA	NA	0.0466	NA	85	1.91E-3	3.84E-4
31	0.62	NA	NA	NA	NA	NA	NA	NA	0.0399	NA	100	1.64E-3	3.30E-4

^aAssumed to represent open cab tree shaker

body

Table 23. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for tree nuts, continued

^bAssumed to represent all other activities

^cDAT = days after treatment.

^dBased on DFR data from a study of postapplication propargite residues on almond using an application rate of 3.0 lb ai/acre (MRID # 418486-03)

[°]Dose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^fShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

^{*}Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

^hFor agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult weight = 70 kg...

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

		Tran	Open cab tr applied at 4. sfer Coefficion	5lb ai/acre	hr ^a			All other activities applied at 4.5lb ai/acre Transfer Coefficient =4,000 cm²/hr ^b					
D A	$(\mu g/cm^2)$ $(mg/kg/day)$ term term MOE^g (Dermal Dose ^e (mg/kg/day)		Short-term MOE ^f	Intermediate-term MOE ^g	LADD ^h	Canceri					
T ^c		BW 60	BW 70	MOE ^f				BW 60	BW 70				
0	4.6	0.0040	0.0035	1500	1160	1.42E-4	2.85E-5	0.3427	0.2938	20	15	1.21E-2	2.43E-3
7	3.21	NA	NA	NA	NA	NA	NA	0.2393	0.2051	25	20	8.43E-3	1.69E-3
14	2.26	NA	NA	NA	NA	NA	NA	0.1671	0.1433	35	30	5.89E-3	1.18E-3
21	1.56	NA	NA	NA	NA	NA	NA	0.1167	0.1000	50	40	4.11E-3	8.26E-3
26	1.21	NA	NA	NA	NA	NA	NA	0.0903	0.0744	65	50	3.18E-3	6.39E-4
28	1.09	NA	NA	NA	NA	NA	NA	0.0815	0.0699	75	60	2.87E-3	5.77E-4
34	0.8	NA	NA	NA	NA	NA	NA	0.0599	0.0514	100	80	2.11E-3	4.24E-4
39	0.62	NA	NA	NA	NA	NA	NA	NA	0.0397	NA	100	1.63E-3	3.28E-4

^aAssumed to represent open cab tree shaker

body

Table 24. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Corn

^bAssumed to represent all other activities

^cDAT = days after treatment.

^dBased on DFR data from a study of postapplication propargite residues on almond using an application rate of 3.0 lb ai/acre (MRID # 418486-03). Data normalized to 4.5 lb ai/acre to account for the application on walnut.

^eDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^fShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

^gIntermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

^hFor agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]. , where adult weight = 70 kg..

Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = $2.01x10^{-1}$ (mg/kg/day)⁻¹

	All activities - Corn applied at 2.46 lb ai/acre Transfer Coefficient =10,000 cm²/hrª											
D A	DFR° (µg/cm²)		mal Dose ^d g/kg/day)	Short-term MOE ^e	Intermediate-term MOE ^f	$LADD^g$	Cancer ^h					
T^{b}		BW 60	BW 70									
0	1.7	0.3243	0.2779	20	15	1.14E-2	2.29E-3					
3	0.96	0.1788	0.1532	35	25	6.30E-3	1.27E-3					
7	0.43	0.0808	0.0693	75	60	2.85E-3	5.73E-4					
9	0.29	0.0544	0.0466	110	85	1.91E-3	3.84E-4					
10	0.24	NA	0.0382	NA	105	1.57E-3	3.16E-4					

^aAssumed to represent all activities

Table 25. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Hops

^bDAT = days after treatment.

 $[\]begin{tabular}{l} cBased on \widehat{DFR} data from a study of postapplication of Propargite (Comite EC^0) on corn using an application rate of 2.46b ai/acre (MRID # 416803-02) dDose (mg/kg/day) = [DFR ($\mu g/cm^2$) x TC (cm^2/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)]. d The sum of the sum of$

[&]quot;Short-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

To agricultural scenarios, LADD = [DFR (µg/cm²) x Tc (cm²/hr) x mg/1,000 µg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]., where adult body weight = 70 kg,.

^hEstimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

			applie	g/irrigation of hop d at 2.51b ai/acre fficient = 4,000 c				Harvesting of hops applied at 2.5lb ai/acre Transfer Coefficient =10,000 cm²/hr ^b					
D A	DFR ^d (μg/cm ²)	Dermal (mg/kg,		Short-term MOE ^f	Inter-term MOE ^g	LADD ^h	Cancer ⁱ	Dermal Dose ^e (mg/kg/day)		Short-term MOE ^f	Inter-term MOE ^g	LADD ^h	Canceri
T ^c		BW 60	BW 70					BW 60	BW 70				
0	5	0.3703	0.3174	15	12	1.52E-2	3.06E-3	0.9258	0.7936	6	5	3.26E-2	6.55E-3
7	3.73	0.2783	0.2385	20	15	1.14E-2	2.29E-3	0.6957	0.5963	9	7	2.45E-2	4.92E-3
10	3.24	0.240	0.210	25	20	8.53E-3	1.7E-3	0.0605	0.5186	10	8	2.13E-2	4.3E-3
14	2.80	0.2091	0.1792	30	20	8.59E-3	1.73E-3	0.5228	0.4481	12	9	1.84E-2	3.70E-3
16	2.54	0.190	0.160	32	25	6.67e-3	1.3E-3	0.4736	0.4060	13	10	1.67E-2	3.4E-3
21	2.10	0.1571	0.1347	40	30	6.46E-3	1.30E-3	0.3928	0.3367	15	12	1.38E-2	2.77E-3
28	1.58	0.1181	0.1012	50	40	4.85E-3	9.75E-4	0.2952	0.2530	20	15	1.04E-2	2.09E-3
45	0.79	0.0506	0.0487	100	80	2.42E-3	4.86E-4	0.1475	0.1264	40	30	5.19E-3	1.04E-3
51	0.62	NA	0.0396	NA	100	1.9E-3	3.82E-4	0.1154	0.0989	50	40	4.07E-3	8.18E-4
67	0.32	NA	NA	NA	NA	NA	NA	0.0601	0.0515	100	80	2.12E-3	4.26E-4
73	0.25	NA	NA	NA	NA	NA	NA	NA	0.0403	NA	100	1.66E-3	3.34E-4

^aAssumed to represent early season activities (weeding and irrigation)

adult

Table 26. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Mint

^bAssumed to represent late season activities/harvesting

^cDAT = days after treatment.

dBased on DFR data from a study of postapplication propargite residues (Omite CR) on hops using an application rate of 1.35 lb ai/acre (MRID # 413996-01) eDose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

^fShort-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day. hFor agricultural scenarios, LADD = [DFR (μ g/cm²) x Tc (cm²/hr) x mg/1,000 μ g x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]., where body weight = 70 kg,.

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = 2.01x10⁻¹ (mg/kg/day)⁻¹

	All activities mint applied at 2.5 lb ai/acre Transfer Coefficient =1000 cm²/hrª										
DAT ^b	DFR ^c (μg/cm ²)										
		BW 60	BW 70								
0	4.55	0.0849	0.0728	70	55	2.99E3	6.01E-4				
3	3.21	0.0600	0.0513	100	80	2.11E-3	4.24E-4				
5	5 2.54 NA 0.0406 NA 100 1.6E-3 3.22E-4										

Assumed to represent all activities for mint

Table 27. Propargite Short-Term and Intermediate-Term Occupational Postapplication Assessment for Cotton

DAT = days after treatment.

Based on DFR data from a study of postapplication Propargite residues on **dry-beans using an application rate of 2.46 lb ai/acre (MRID #426891-04)** Dose (mg/kg/day) = [DFR (μ g/cm²) x TC (cm²/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

Short-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 6 mg/kg/day.

Intermediate-term MOE = NOAEL (mg/kg/day) / Dose (mg/kg/day); where NOAEL = 4 mg/kg/day.

For agricultural scenarios, LADD = [DFR $\mu g/cm^2$) x Tc (cm²/hr) x mg/1,000 μg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]., where adult body weight = 70 kg,.

Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = $2.01x10^{-1}$ (mg/kg/day)⁻¹

	Weeding/hoeing application rate 1.64 lb ai/acre Transfer coefficient 63.0 cm²/hrª						Scouting early season application rate 1.64 lb ai/acre Transfer coefficient 1,000 cm²/hr ^b				Scouting late season application rate 1.64 lb ai/acre Transfer coefficient 4,000 cm²/hr²								
D A	DFR ^e (µg/cm ²)	Derma (mg/k		Short- term	Inter- term	LADD ⁱ	Canceri		l Dose ^e (g/day)	Short- term	Inter- term	LADD°	Canceri	Dermal (mg/kg		Short- term	Inter- term	LADD°	Canceri
T ^a		BW 60	BW 70	MOE ^g	MOE ^h			BW 60	BW 70	MOE ^f	MOE ^g			BW 60	BW 70	MOE ^f	MOE ^g		
0	2.0	0.0023	0.0020	2630	2050	8.04E-5	1.62E-5	0.0368	0.0316	165	125	1.30E-3	2.61E-4	0.1473	0.1263	40	30	5.2E-3	1.05E-3
3	1.39	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.1038	0.0890	60	45	3.7E-3	7.44E-4
8	0.78	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0580	0.050	105	80	8.7E-3	4.26E-4
10	0.62	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0394	NA	100	6.9E-3	3.36E-4

^aAssumed to represent weeding/hoeing

body

4.3.3 Incident Information

PROPARGITE REVIEW

^bAssumed to represent scouting early season

^cAssumed to represent scouting late season

^dDAT = days after treatment

Based on DFR data from a study of postapplication of Propargite (Comite EC ®) on cotton using an application rate of 1.64 ai/acre (MRID # 414578-06)

¹Dose (mg/kg/day) = [DFR (μ g/cm2) x TC (cm2/hr) x CF (1 mg/1,000 mg) x ET (hrs) / BW (kg)].

 $^{{}^}gShort-term\ MOE = NOAEL\ (mg/kg/day)\ /\ Dose\ (mg/kg/day);\ where\ NOAEL = 6\ mg/kg/day. \\ {}^hIntermediate-term\ MOE = NOAEL\ (mg/kg/day)\ /\ Dose\ (mg/kg/day);\ where\ NOAEL = 4\ mg/kg/day. \\$

For agricultural scenarios, LADD = [DFR (µg/cm2) x Tc (cm2/lrr) x mg/1,000 µg x hours exposed/day x exposure days/year x years of exposure x dermal absorption factor] / [body weight in kg x 70 yr x 365 days/yr]., where adult weight = 70 kg.

¹Estimated Cancer Risk = LADD (mg/kg/day) x Q1* (mg/kg/day), where Q1* = $2.01x10^{-1}$ (mg/kg/day)⁻¹

Incident Data System

The following cases from the OPP Incident Data System (IDS) do not have documentation confirming exposure or health effects unless otherwise noted.

Incident#1280-23

A pesticide incident occurred in 1994, when a spray applicator got the chemical in his eyes. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

Incident#4066-12

A pesticide incident occurred in California in 1996, when 49 field workers lifted canes in grape fields that were wet with dew. Many of the workers clothes became soaking wet and they experienced burning, itching, and a rash on their arms, neck, chest, and stomach. From information collected by the Agricultural Commissioner's staff it appeared that the label was followed. There was evidence of non-compliance with the re-entry interval of 30 days. Results from analysis of foliage samples confirmed residues of propargite on the grape foliage. All of these workers were seen at the primary medical care center. No further information on the disposition of the case was reported.

Incident#5995-1

A pesticide incident occurred in 1997, when five workers experienced skin and eye irritations after formulating and packaging a chemical which was caused by abnormally high levels of dust being generated in the pack-room. No further information on the disposition of the case was reported.

Incident#7346-1

A pesticide incident occurred in 1985, when a worker was inadvertently drenched with spray from an air blast sprayer used to treat a grape vineyard. The worker experienced vomiting within thirty minutes and later developed chronic asthma and other respiratory problems. These symptoms were not consistent with exposure to propargite and there may have been exposure to a second pesticide

that was responsible for these symptoms. No further information on the disposition of the case was reported.

Poison Control Center Data - 1993 through 1996

From 1993 through 1996 there were 62 exposures to propargite reported to Poison Control Centers participating in the Toxic Exposure Surveillance System. A total of 40 of these exposures were reported to be non-occupational including 33 adults and children six years old and over and seven children under age six. Twenty-two cases of exposure were reported to be occupationally related. Twenty-one of these cases occurred in California and therefore may also be reported in the section below concerning California data. No detailed analysis is performed because there were too few cases in any one category. Of the total cases 23 were reported to have a minor medical outcome and three cases were reported to have a moderate medical outcome. There were no fatalities or life-threatening cases. The most common symptoms reported included nausea, oral irritation, chest pain, dizziness, headache, and eye and dermal effects. A total of 25 of these cases were seen in a health care facility, however, none were admitted for hospitalization.

California Data - 1982 through 1996

Detailed descriptions of 923 cases submitted to the California Pesticide Illness Surveillance Program (1982-1996) were reviewed. In 671 of these cases, propargite was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Propargite ranked 44th as a cause of systemic poisoning in California for the years 1982-1994. All of the systemic cases reported in this period were in an agricultural setting with roughly one-third occurring among handlers and two-thirds among field workers.

Table 30 presents the types of illnesses reported by year for the time period 1982 through 1996. Table 31 gives the total number of workers that took time off work as a result of their illness and how many were hospitalized and for how long.

Table 28. Cases Due to Propargite Exposure in California Reported by Type of Illness and Year, 1982-1996.

	ses Bue to Frapaig		Illness Type	oj ijpo	
Year	Systemic ^b	Eye	Combination. ^c	Skin	Total
1982	2	9	2	40	53
1983	6	18	5	24	53
1984	3	13	4	63	83
1985	1	9	-	37	47
1986	-	7	1	143	151
1987	1	5	4	25	35
1988	3	7	-	81	91
1989	3	3	-	6	12
1990	5	4	1	7	17
1991	-	3	-	3	6
1992	-	5	-	15	20
1993	2	4	-	4	10
1994	3	2	1	5	11
1995	2	-	-	70	72
1996	2	2	1	5	10
Total	33	91	19	528	671

Category includes cases where skin, eye, or respiratory effects were also reported.
 Category includes combined irritative effects to eye, skin, and respiratory system.

Table 29. Number of Persons Disabled (taking time off work) or Hospitalized for Indicated Number of Days After Propargite Exposure in California, 1982-1996.

	Number of Persons Disabled	Number of Persons Hospitalized
One day	55	-
Two days	25	-
3-5 days	50	-
6-10 days	18	-
more than 10 days	4	-
Unknown	161	5

A total of 528 persons had skin illnesses or 79% of 671 persons. Data covering the years 1982-1989 found that propargite was the leading cause of skin-related injuries among all pesticides. For the years 1990-1994, propargite dropped to seventh place among specific active ingredients. Worker activities associated with exposure to propargite are presented in Table 32 below.

Table 30. Illnesses by Activity Categories for Propargite Exposure in California, 1982-1996.

·			Illness Ca	ategory	
Activity Category	Systemic ^b	Eye	Skin	Combination ^c	Total
Applicator	7	45	64	10	126
Mixer/Loader	3	22	35	4	64
Coincidental	2	4	9	2	17
Field Residue	13	14	411	3	441
Drift	5	-	3	-	8
Other	2	6	7	-	15
Total	32	91	529	19	671

^a Coincidental=accidental exposure to application strength dilution but not directly involved in pesticide handling activity; Drift= exposure to pesticide that has drifted from intended targets.

According to the above activity categories, field residue was associated with the majority (66%) of the exposures. These illnesses included symptoms of chest tightness, shortness of breath, headache, sore throat, coughing, dermatitis, rash on arms, neck, chest and eyes, and eye irritation. In 1988, 26 workers harvesting nectarines developed rashes in orchards treated with propargite and two other pesticides. Samples of foliar dislodgeable residues suggested that propargite was the cause of the dermatitis cases.

^b Category includes cases where skin, eye, or respiratory effects were also reported

^c Category includes combined irritative effects to eye, skin, and respiratory system

Dermatitis developed in 114 orange pickers in a single incident in 1986. One-third of the workers developed peeling indicating severe dermatitis (Saunders et al. 1987). As a result of this and other large outbreaks the reentry interval was extended from 2-7 days (depending on crop) to 14-42 days in 1989 resulting in a significant reduction in propargite-related illness (Mehler et al., 1992).

National Pesticide Telecommunications Network

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, propargite was ranked 116th with 28 incidents in humans reported and three incidents in animals (mostly pets).

According to California data, it appears that a majority of cases involved skin illnesses some of which can be quite severe requiring extensive time off work to recover. A large proportion of cases resulted from field reentry and worker activities involving extensive contact with treated foliage such as turning cane for grapes and harvesting citrus. Both eye and skin problems are commonly reported among applicators who handle propargite without proper protection.

5.0 AGGREGATE RISK ASSESSMENTS AND RISK CHARACTERIZATION

5.1 Acute Aggregate Risk

There are no registered residential uses of propargite so acute aggregation will include only food and water.

Acute DWLOCs were calculated based on the acute dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the acute DWLOCs, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The acute DWLOC for Females 13-50 years is 2400 ppb. The GENEEC surface water value is 69 ppb.

The EECs for groundwater (SCI-GROW) were less than the acute DWLOC's, indicating that acute aggregate exposure to propargite in food and water is less than HED's level of concern. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). To calculate the DWLOC, the acute dietary food exposure was subtracted from the acute PAD using the equation:

where acute water exposure (mg/kg/day) = [aPAD - (acute food (mg/kg/day))]

Table 31. Drinking Water Levels of Comparison for Acute Dietary Exposure.

Population Subgroup	Acute PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	DWLOC _{acute} (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
Females 13-50 years	0.08	0.001	0.08	2400	69	0.006

5.2 Short- and Intermediate-Term Aggregate Risks

There are no registered residential uses of propargite, therefore, short- and intermediate-term aggregation is not appropriate.

5.3 Chronic Aggregate Risk

There are no registered residential uses of propargite, therefore, chronic aggregation will include only food and water.

Chronic DWLOCs were calculated based on the chronic dietary (food) exposure and default body weights and water consumption figures. The EECs for surface water (GENEEC) were less than the chronic DWLOCs, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The EECs for groundwater (SCI-GROW) were less than the chronic DWLOC's, indicating that chronic exposure to propargite in food and water is less than HED's level of concern. The Agency's default body weights and water consumption values used to calculate DWLOCs are as follows: 70 kg/2L (adult male), 60 kg/2L (adult female), and 10 kg/1L (child). To calculate the chronic DWLOC, the chronic dietary food exposure was subtracted from the chronic PAD using the equation:

$$DWLOC_{chronic}(ug/L) = \underbrace{[chronic\ water\ exposure\ (mg/kg/day)\ x\ (body\ weight\ in\ kg.)]}_{[consumption\ (L/day)\ x\ 10^{-3}\ mg/\ \mu g]}$$

where chronic water exposure (mg/kg/day) = [cPAD - (chronic food (mg/kg/day))]

Table 32. Drinking Water Levels of Comparison for Chronic Dietary Exposure.

Population Subgroup	Chronic PAD (mg/kg/day)	Food Exposure (mg/kg/day)	Max. Water Exposure (mg/kg/day)	DWLOC _{chronic} (ug/L)	GENEEC (ug/L)	SCI-GROW (ug/L)
US Population	0.04	0.00001	0.04	1400	7.6	0.006
All Infants	0.04	0.00001	0.04	400	7.6	0.006
Children 1-6	0.04	0.00001	0.04	400	7.6	0.006
Children 1-12	0.04	0.00001	0.04	400	7.6	0.006
Females 13-50 yrs.	0.04	0.00001	0.04	1200	7.6	0.006
Males 20+ yrs	0.04	0.00001	0.04	1400	7.6	0.006

5.4 Cancer Aggregate Risk

There are no registered residential uses of propargite so cancer aggregation will include only food and water.

Cancer DWLOCs were not calculated because cancer dietary (food) risk was at 1.0 X 10⁻⁶. Exposure to propargite from drinking water derived from groundwater sources is minimal and would not contribute significantly to the cancer risk. Surface water concentrations below 0.2 ppb would result in cancer risks below 1 X 10⁻⁶ for drinking water alone when back calculated. Time weighted average propargite concentration in surface water samples from the USGS NAWQA (Oristimba Creek Watershed) for the years 1992-1993 were 0.30 and 1.24 ppb, respectively. Therefore, even when monitoring data are used cancer exposure to propargite from surface water sources is greater than HED's level of concern.

6.0 DATA NEEDS

Additional data requirements have been identified in the attached Science Chapters and are summarized below.

Toxicology Data for OPPTS Guidelines: None required.

Product and Residue Chemistry Data for OPPTS Guidelines:

OPPTS GLN 830.7050 (UV/Visible absorption)

OPPTS GLN 860.1200 (Directions for Use) - Label revisions are required.

OPPTS GLN 860.1380 - Additional storage stability data are required for peanut, walnut, corn, and tea..

OPPTS GLN 860.1520 - Additional residue data are required for cotton gin byproducts.

Occupational Exposure Data for OPPTS Guidelines: None required.